(19) World Intellectual Property Organization International Burcau



. I DE LE COLLEGE DE C

(43) International Publication Date 30 May 2002 (30.05.2002)

PCT

(10) International Publication Number WO 02/41932 A2

(51) International Patent Classification7:

A61M

(21) International Application Number:

PCT/IL01/01070

(22) International Filing Date:

20 November 2001 (20.11.2001)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

139802

21 November 2000 (21.11.2000)

(71) Applicant (for all designated States except US): SER-POMED LTD. [II] P.O. Box 4583, 84144 Beer-Sheva (II.).

(72) Inventor; and

(75) Inventor/Applicant (for US only): POPOV, Sergey [II/IL]: 32/17 Alexander Yanai Street, P.O. Box 4583, 84144 Beer-Sheva (IL).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

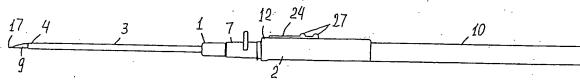
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

 without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CATHETER INSERTION APPARATUS



(57) Abstract: This invention relates to catheter insertion devices with a needle tip protective system (see fig. 59) for peripheral blood vessel catheterization. The device comprises a handle and a needle hub disposed inside the handle and including a flash chamber. A needle is affixed to the needle hub and extends through the passageway in the handle and a catheter unit. A trigger member associated with the handle retains the needle unit in distal, duty ready position. A securing member preventing the trigger member from accidental actuating is slidably disposed on exterior upper surface of the handle, has a functional connection with the catheter hub including unremovable connection version, and is adapted to pushing the catheter unit distally by the same user's hand that holds the device. This pushing leads to actuating the trigger member and, as a result, to transposing the needle sharp point automatically by a spring or manually into protected security zone. The securing member is also an obligatory securing member preventing the catheter unit from disconnecting from the needle assembly until the needle unit is transposed into protected position. The device additionally can be provided with an unidirectional motion mechanism eliminating catheter damage by a needle sharp end, as well as an expandable sleeve interconnecting shortened handle with the needle hub and substantially shortening the device in its duty ready position.

O 02/41932 A2

CATHETER INSERTION APPARATUS

Field of Invention

This invention is generally related to intravascular catheters and such catheters placement devices and more particularly, to catheter placement devices for peripheral blood vessel catheterization with needle tip protective systems.

Background

Catheterization of peripheral blood vessels by a short catheter mounted on a hollow needle is one of the most widely used medical manipulations jeopardizing the medical personnel by blood-transmitted hazardous infectious diseases. As a rule, the personnel become infected through accidental pricking by a needle extracted out of catheter. To prevent such injuries, safety systems protecting from accidental contact with the used needle tip are developed. All types of known needle tip protectors can be subdivided into two groups - those where the needle is displaced into protective position by a spring, and those where a needle is manually displaced to the protective position. Greater or lesser efficiency of such devices depends on due consideration in design of all manipulation stages, the individual features of their users and the extensive variety of catheterization conditions. Recognition of new designs by the users, promptness and extension of their widely spread implementation in everyday practice depend on the device ergonomics, their reliability, and, last but not least, on the device price, which is greatly dependable on the design complexity and production labor consumption. In view of the above said, the device for catheterization of peripheral blood vessels should meet the below specified criteria as best as possible:

Presence of means precluding accidental trigger start in the devices with springy displacement of needle. Blood vessel catheterization is an intricate manipulation, requiring maximal concentration of attention, and when it is made by the device with springy displacement of needle, various accidental trigger-affecting factors may be involved, that will result in the premature needle extraction out of catheter, the manipulation should begin anew and with a fresh device. It is evident that the devices

with springy needle displacement and equipped with the means preventing accidental trigger start reduce the probability of such events.

Presence of means ensuring complete disconnection of needle assembly and catheter unit only after the needle enters the protected position.

Both above mentioned requirements are sure to be held not at the expense of the device ergonomics, and the device which ensures needle placement to the protected position, following conventional manipulations, without any special operator's actions, meets them most perfectly.

Presence of means precluding needle removal out of catheter before catheter is sufficiently deeply inserted into blood vessel lumen. The significance of this property is explained by the fact that at the initial stage of catheter insertion into the blood vessel lumen the needle acts as a conductor and as a member precluding the catheter bends. Any of known devices of this class is not equipped with such means.

Presence of means preventing needle return to the initial position concerning catheter. An attempt to return needle to its starting position after the start of needle extraction out of catheter, or after the start of the catheter removal from the needle is a grave violation of short catheter operation instructions that might result in the breakage of catheter wall integrity by a needle, and even in complete cutting a catheter section, which in the first case, results in tissue injury in the manipulation area, whereas in the second case, the cut catheter section can get into blood flow.

Presence propelling means of catheter distal advance concerning of needle, operated by the same hand, which holds the device during the blood vessel puncture. A valuable feature of such devices is the possibility of executing major catheterization stages by one hand only, thus releasing the user's second hand for other actions. In known devices in which the needle is displaced in protected position by spring a principle of advance of a catheter by one hand is not realized, in particularly because after catheter hub is removed from needle hub to a distance of several millimeters, the catheter becomes freely pivotable on the needle around its axis, therefore smooth introduction of a catheter to a vein requires the assistance of the second hand.

The cannula insertion set with safety retracting needle is disclosed by the US Patent 4747831. The described device has springy mechanism, which displaces the needle into a hollow protector. The springy mechanism has the trigger button accessible for finger control on the protector upper side. As the access to the button is free the accidental

pressure on the button can prematurely release a spring, which displaces a needle in protected position and consequently the manipulation should be started anew. On the other hand, needle unit can be disconnected from catheter unit before the needle displacement to protected position that enhances the possibility of pricking the user by the needle. In the described device is absent means eliminating the needle movement into distal position with respect to a catheter, and it threatens with known complications. The inconvenience in handle of the device with the help of one hand has an negative effect for speed and quality of catheterization as a whole.

The intravenous catheter assembly with automatic cannula tip guard is disclosed by US Patent 5599310. According to the authors' idea, a protector should become disconnected from catheter hub only after the needle sharp point will be placed in protected position. However, the described mechanism does not ensure reliable execution of the benefits declared by the patent, since the reliability of guard engagement with catheter hub depends on the height of detents and on the depth of their penetration into corresponding recesses made in the catheter hub wall. It is evident, that the less is the needle diameter the less can be the height of detents, which, as it follows from the device operation principle, is always less than one half of the needle diameter, hence for the 0.5-mm diameter needle the detent height must not exceed 0.25 mm. Such dimensions of the engaging members cannot ensure the reliable mount of protector to hub of catheter. The problem of protector fixation reliability in catheter hub takes place in main in devices with the needle of a small diameter. However, a manufacture complexity is inherent in all devices constructed according to the described principle. The disadvantage of the device is that the connection of needle assembly with catheter unit can begin only after the needle will be disposed between fingers of protector and in such position its dimensions are enlarged that complicates entry of protector in catheter hub. During removal a needle from a catheter, detaching the protector from catheter hub almost always will take place before the needle is transposed into protected position. It occurs because the resilient finger returns to spring biased position as soon as the needle section median point approximately reaches its level, i.e. guard disengagement with catheter hub occurs prematurely. Moreover, because in this case only minor section of needle tip protrudes from the guard, the operator loses his vigilance and is more prone to needle prick.

Two types of flash chambers in catheter insertion apparatus with springy needle displacement to protected position are known: movable flash chamber fixed on the needle proximal end, and stable flash chamber, the protector cavity serving as such. The disadvantages of movable flash chamber are additional accessories increasing device sizes and degrading observation conditions of blood appearance in the chamber caused by an additional obstacle of chamber wall. The demerits of the devices equipped with stable flash chamber are their high production cost, stemming from strict requirements to the detail manufacturing accuracy and their assembly, and possible active air injection from the camera to the needle, and subsequently, to a patient's vein, by the needle displacement to protected position.

A catheter and needle placement assembly with retractable needle having a stable flash chamber is disclosed by US Patent 5797880. According to this patent, flash chamber and needle have sealing: a valve mounted on the needle proximal end, and fluid tight seal of opening in distal wall of flash chamber with an outside surface of needle. The disadvantage of this construction consists in that the valve is additional barrier to the blood flow from the needle to flash chamber, which may hamper the detection of needle location in vein lumen, when the venous blood pressure is low. Such valve is very tiny, which results in the product high cost. Presence of fluid seal member makes the assembly cumbersome and increases the product cost.

Self-contained safety intravenous catheter insertion device is disclosed by US Patent 6056726. This device comprises the self-contained coupling means for preventing the separation of the catheter from the device until the needle is transposed into safety receptacle as well as automatic needle transposal means triggered within the interior of the safety receptacle for transposing the needle into the receptacle. Said coupling means includes a distal part of the receptacle holding member and a catheter holding member releasably attached to the catheter. Said transposal means includes a spring, the receptacle holding member and the latch member which is immovably attached to the needle and has biased projection slidably located in the notch of the receptacle and held there by pressure from contact with said receptacle holding member.

In the period of initial catheter displacement in distal direction with respect to the needle, i.e. into patient's vein, said biased projection of the latch member pushes the latch member upwards in response of the spring effect and thereby the latch member presses onto the receptacle holding member. This causes significant friction between the

POCID: <WO 024193242.4

receptacle holding member, the receptacle and the latch member and, as a result, impedes said displacement and does not enable the user to sense the patient's tissue resistance. This disadvantage is the consequence of said immovable attachment of the latch member to the needle and of triggering the needle transposing means within the interior of the safety receptacle by means of the receptacle holding member, the latch member and corresponding notch disposed within the interior of the safety receptacle. Last feature is in all independent claims of this patent.

Another disadvantage of US Patent 6056726 is the absence of the means preventing needle return to the previous position with respect to the catheter after the start of needle withdrawal out of the catheter. That can lead to the injury of the catheter wall and even to its complete cutting.

Another disadvantage of the US Patent 6056726 is the impossibility to operate with the device by user's one hand because of the absence of plurality propelled projections on upper surface of the receptacle holding member as well as because of supporting only proximal end of the receptacle holding member by the receptacle. The latter can cause the curvature of receptacle holding member position and as a consequence an increased friction and even a jam in the zone of the contact between the receptacle and the receptacle holding member.

Another disadvantage of the US Patent 6056726 is that the needle is the member of self-contained coupling means. As such, the needle impedes the displacement of the catheter in transverse direction with respect to the receptacle holding member and therefore the needle is subjected to transverse forces effect. That can lead to such undesirable consequences as the injuries of catheter wall by needle sharp tip, beveling the latch member position and other. Besides, there is possibility of the disconnection of receptacle holding member and the catheter until the needle is transposed into protected position.

Note that the device according to US Patent 6056726 does not comprise any means for the improvement of catheter fastening to the patient's skin.

Another disadvantage of the US Patent 6056276 is excessive complexity of device design posing great problems for device assembly and causing significant growth of its cost.

Thus, there are not any patents in the prior art disclosing the features enabling to meet all specified criteria noted above.

Summary of the Invention

The invention objective is increased performance reliability of the device by prevention of unconscious starting trigger means in the devices with springy mechanism of needle removal to protected position.

Another invention objective is advanced safety properties of the device by the prevention of complete needle assembly disconnection from catheter unit before needle is displaced to protected position.

Another invention objective is prevention of the unconscious starting of trigger before the needle is removed from catheter unit at a definite given distance.

Another invention objective is ruling out emergencies and complications during the device operation by prevention of the needle return movement distally to catheter after the needle removal out of catheter has begun.

Another invention objective is improving the ergonomics of catheter placement apparatus with springy mechanism of needle displacement to protected position by propelling means adapted to the displacement of said catheter unit to inserting direction distally of said needle unit and/or for fixation of said catheter unit in a blood vessel upon withdrawing said needle unit out of said catheter unit and disconnection of said needle assembly from said catheter unit, and made in such a manner that all manipulations are performed with user's one hand only.

Another invention objective is increased convenience and reliability of catheter fastening to the patient's skin.

Another invention objective is reduced dimensions of the assembly.

Another invention objective is preclusion of air entering the patient's blood flow.

Another invention objective is improved observation conditions of blood outflow from the needle to flash chamber.

The above noted objectives of the present invention are accomplished by catheter insertion apparatus including: a catheter unit; a needle assembly with a guard member, a needle sharp point guard, a handle and a needle unit with tubular needle; a spring to urge the needle unit to a protected position; a trigger means having a trigger member made as a latch; a trigger securing means; an obligatory securing means; a trigger start

beginning defining means; unidirectional motion means; a propelling means; an attachment means; a stopping means.

Said triggering means is designed for triggering off the needle unit transposition into the protected position. Unlike the prior art (see US Patent 6056726), said trigger means has the latch which is movable with respect to the needle and means for its actuating are located outside the handle or guard member. As a result, said trigger means does not create any friction during the catheter displacement into patient's body and does not hamper the user to sense a patient's body resistance.

Said trigger securing means is designed for preventing unconscious starting the trigger means and has a securing member with start trigger prevention position, wherein the trigger means start is impossible, and start trigger ready position, wherein the trigger means is ready for the activation. The securing member is made as a screen, which in the start trigger prevention position hampers direct approach of user's finger to the trigger member. The trigger means can be activated automatically or manually. In last case the security member in start trigger ready position opens direct approach of user's finger to the trigger member.

Said obligatory securing means is designed for preventing the disconnection of the needle assembly from the catheter unit in all events until the needle unit is displaced to the protected position. The obligatory securing means comprises an actuating means made as obligatory automatically starting actuating means having the securing member and the actuating member functionally connected together and to the catheter unit at least until the trigger means starts as a result of further displacement of the catheter unit with respect to the handle in distal direction. Said obligatory securing means unlike US Patent 6056726 do not creates the transverse load onto the needle and therefore do not causes the injury of the needle and the catheter as well as rules out quite the disconnection of the catheter unit and the needle assembly.

Said trigger start beginning defining means is designed for the prevention of unconscious starting the trigger means before the needle unit is displaced from the catheter unit to a definite given distance. In version embodiment the trigger start beginning defining means is made as the actuating member situated at a predetermined distance from the catheter hub. Such actuating member provides starting the trigger means only on reaching said definite given distance.

Said stopping means are designed for stopping the securing member in a start ready position. This stopping serves as a signal for the user to actuate the trigger means. In version embodiment the stopping means includes the distal edge of elongate slot in the guard member and the stopping surface connected with movable needle hub. In version embodiment with manual controlled actuating member such stopping means fulfils the role of the abovementioned obligatory securing means and the trigger start beginning definite means. The stopping means of such designation is absent in the prior art quite. Said unidirectional motion means are designed for providing the needle unit displacement only in a proximal direction with respect to the catheter unit and excluding the possibility of return displacement. This means is made as interacting toothed engagement members situated on the securing member and the handle along the needle assembly longitudinal axis.

Said propelling means is designed for the apparatus control by the user, provides functional interacting of the catheter unit with the needle unit, is adapted to the displacement of the catheter unit in the inserting direction distally with respect to the needle unit and for fixing the catheter unit in a blood vessel upon withdrawing the needle unit out of the catheter unit and the disconnection of the needle assembly from the catheter unit. The propelling means includes plurality propelled projections located on the member which is connected with the catheter unit and movable with respect to the needle unit, for instance on the securing member or the guard member, so that at least part of the propelled projections is disposed in the operating zone within reach of the fingers of the user's hand which holds the apparatus at its handle. Moreover, said part of the propelled projections is always supported by the handle or the details adjacent to the handle. Unlike US Patent 6056726, the present propelling means enables to operate the apparatus only by user's one hand and does not causes the increased friction or jams in a needle unit drive.

Said attachment means is designed for the improved fixation of the catheter unit to a patient's skin and has an attachment member situated on the catheter hub. The securing member is applied as the attachment member. Such securing member is pivotably connected to the catheter hub and, after complete disconnection of the catheter unit from the needle assembly, the securing member is turned through 180° around the point of its mounting towards the catheter hub and is used for the fixation of the catheter unit

on the patient's skin. Such two-functional attachment means is not disclosed quite in the prior art.

Thus, the above described means provide the accomplishment of the present invention objectives and are not disclosed in the prior art.

Drawing Figures

The present invention description includes 90 Figures. For more convenient consideration these Figures are presented as following groups and subgroups.

- 1. FIGS. 1 to 68 show the catheter insertion apparatus with the needle displaced into a protective position by spring.
- 1.1. FIGS. 1 to 33 show the apparatus wherein the gripping and guard members are immovable to one another and are carried out as a single unit.
- 1.1.1. FIGS. 1 to 6 show the apparatus with the securing member movably mounted on the needle assembly and direct manual control of the trigger means as well as with movable flash chamber.
- 1.1.2. FIGS. 7 to 15 show the apparatus wherein the securing member is connected unremovably with the catheter unit and there are automatic control of the trigger means, the attachment means for fastening the catheter hub to patient's skin and stable flash chamber.
- 1.1.3. FIGS. 16 to 23 show the apparatus wherein the security member has removable functional connection with the catheter unit and its trigger means has automatic control.
- 1.1.4. FIGS. 24 to 33 show the apparatus wherein are the securing member applying for propelling the catheter unit, the trigger means having the direct manual control, unidirectional motion means, stopping means and attachment means.
- 1.2. FIGS. 34 to 49 show the apparatus wherein the guard member is movable with respect to the handle.
- 1.2.1. FIGS. 34 to 41 show the apparatus with automatic trigger start.
- 1.2.2. FIGS. 42 to 49 show the apparatus with indirect manual control of the trigger means and with stopping means.
- 1.3. FIGS. 50 to 68 show the apparatus having shortened handle with applying an expandable sleeve.

- 1.3.1. FIGS. 50 to 56 show the apparatus with direct manual control of the trigger means.
- 1.3.2. FIGS. 57 to 68 show the apparatus with automatic control of the trigger means and with removable attachment means.
- 2. FIGS.69 to 90 show the catheter insertion apparatus with manual displacement of the needle into protective position.
- 2.1. FIGS. 69 to 84 show the apparatus wherein the engagement of the needle assembly and the catheter unit is situated inside the catheter hub.
- 2.1.1. FIGS: 69 to 76 show the apparatus adapted to the thin needles.
- 2.1.2. FIGS. 77 to 84 show the apparatus adapted to the thick needles.
- 2.2. FIGS. 85 to 90 show the apparatus with threaded connection of the catheter unit and the needle assembly.

Detailed Description of the Invention

A typical embodiment of the catheter insertion apparatus with the needle displaced into protected position by spring is shown in FIG.1 to 6. FIG.1 is a side view of the apparatus, FIG.2 is its top plan view, FIG. 3,5,6 are longitudinal cross sections and FIG.4 is transverse cross section of said apparatus in plane 4-4 made in FIG.3. The apparatus is composed of two main parts: a catheter unit 1 and a needle assembly 2. The catheter unit 1 consists of a catheter 3 with a distal end 4, a proximal end 5 and an open passageway 6 as well as a catheter hub 7 affixed to the proximal end 5. The needle assembly 2 includes: a proximal end 8 and a distal end 9 with catheter hub7 removably connected therewith; a handle 10 with an open bore 11; a needle guard means 12, having a sharp point guard 13 with security zone 14; a needle unit 15 having a tubular needle 16 with a distal sharp point 17, a proximal end 18 and a needle hub 19 affixed to the proximal needle end 18. The needle 16 has an initial extended position, shown in FIG.1, 2, 3, 4, wherein the needle 16 is disposed within the open bore 11 of the handle 10 and the catheter passageway 6 so that the distal point 17 of the needle 16 projects axially beyond the distal end 4 of the catheter 3 and the needle 16 and its sharp distal point 17 are in extreme distal position with respect to the sharp point guard 13. The needle assembly 2 includes as well a spring 20 interacting with the needle hub 19 to urge needle unit 15 to a protected position, shown in FIG. 6. The needle sharp distal point 17 in this position is permanently retained within the security zone 14 so that any accidental

contact with the sharp distal point 17 is impossible. Moreover the needle assembly 2 is provided with a trigger means 21, having a trigger member 22 associated with the handle 10. The trigger member 22 has locking position, shown in FIG.3, 4, 5, wherein it retains the needle unit 15 in distal position with respect to the handle 10. There is as well the releasing position of the trigger member 22, shown in FIG.6, wherein the trigger member 22 is displaced downward and does not preclude from moving of the needle unit 15 under spring 20 action in proximal direction with respect to the handle 10. Said catheter insertion apparatus is provided with a trigger securing means 23 with a securing member 24 for the prevention of unconscious starting the trigger means 21. The securing member 24 made as a screen over the trigger means 21 has a start trigger prevention position, shown in FIG. 1,2,3,4, wherein the trigger means start is impossible because the securing member 24 shuts the button 25 of the trigger member 22 and does not enable to press it. There is as well a start trigger ready position, shown in FIG. 5,6, wherein the trigger means 21, in particularly its button 25, is opened for direct manual activation because the securing member 24 is displaced in proximal direction. Therefore this trigger member 22 relates to a direct operated trigger member. The securing member 24 is movably mounted in guide grooves 26 of the handle 10 and has two projections 27. In version embodiment the securing member has flexible rotated connection with the handle 10 by its distal or proximal end (not shown) and to displace the securing member into the start trigger ready position it has to be rotated around its connection place.

The apparatus with the needle 16 in the initial extended position (see FIG. 3) is introduced into patient's vein. As a result the blood gets into the transparent flash chamber 28 through the tubular needle 16. The flash chamber 28 is made as a movable chamber and presents a hollow member located in a longitudinal cavity inside the handle 10 and mounted on the proximal needle end 18. The flash chamber 28 has the communications with the passage of the tubular needle 16 and with the air through the vent diaphragm made in the form of the plug 29. The plug 29 of the flash chamber 28 is made of porous material penetrated for the air and non-penetrated for the blood. Therefore the air can go out of the flash chamber 28 during its filling by the blood. The appearance of the blood in the flash chamber 28 serves as the indication of successful penetrating of the needle 16 into the vein. Then the user propels the catheter unit 1 into the blood vessel applying the needle 16 as a guide and forming some distance between the catheter hub 7 and the sharp point guard 13 as it is shown in FIG.3. Further the user propels the projections 27 and thereby displaces the securing member 24 in

proximal direction into the start trigger ready position, shown in FIG.5. After that, the user presses the button 25 downward displacing the trigger member 22 into the releasing position. As a result, the spring 20 displaces the needle unit 15 in proximal direction into rearward position in the longitudinal cavity of the handle 10 and completely disconnects the needle assembly 2 and the catheter unit 1. Lastly, the sharp distal point 17 of the needle 16 gets into security zone 14 and remains there preventing medical personnel from pricking by the sharp distal point 17. Thus, the presence of the trigger securing means 23 completely prevents from occidental disconnection of the catheter unit 1 and the needle assembly 2. Note that the trigger member 22 is made as a latch movable with respect to the needle unit 15. In locking position (see FIG.3, 5), it effects its locking actions by its lateral loaded surfaces and is displaced into release position by trigger means, in particularly the button 25, located outside the internal cavity of handle 10. Owing to that, the trigger member 22 does not hamper the catheter unit 1 displacement in distal direction, unlike US Patent 6056726 where the locking action is effected by outside peripheral loaded face of the latch, hampering the distal displacement of the catheter. Moreover, the trigger member 22 in the release position (see FIG.6) obtained as a result of its displacement downward as well does not create any obstacles for the displacement of the needle unit 15 into the protected position. The version embodiment of the catheter insertion apparatus, shown in FIG. 7 to 15, has the designations of the details with additional first numeral 1. This version and previous version relate mainly to the same type of the apparatus with the needle displaced into the protected position by the spring. In connection with that, the description of the previous version relates to the details of the present version with identical numerals considered without said additional first numeral. At the same time, FIG.7 to 15 include several substantial distinctions, which are described below.

The securing member 124 in FIG. 7 to 15, designed for preventing unconscious starting the disconnection of the catheter unit 101 and the needle assembly 102, is made as a single unit; with the catheter unit 101 and connects with it by means of flexible rotational member 130. Moreover, the securing member 124 is movably situated in the guide grooves 126 of the handle 110. Besides, the apparatus comprises the actuating means including the actuating member 131 in form of a cam for mediate control of the trigger means 122. The actuating member 131 is located on the lower surface of the securing member 124 and is movable between an idle position shown in FIG.9 and a trigger position shown in FIG.11. It is as well provided with outer projections 127. The apparatus has a stable flash chamber 132 presenting

longitudinal cavity which has a resilient tight gasket 133 between the needle hub 119 and the handle 110 situated more proximally than distal outlet openings 111 and 134 in the body of the handle 110. The proximal opening 136 of this cavity is covered by the vent diaphragm 137 made of the material penetrated for the air and non-penetrated for the blood. Moreover, there is a small gap 135 between the needle hub 119 and the handle 110 sufficient for air penetrating into the flash chamber 132.

After introducing the needle distal sharp point 117 into patient's vein and the appearance of the blood in the flash chamber 128, the user propels the projections 127 of the securing member 124 in distal direction by the finger of the same hand, which holds the apparatus. Herewith, the user displaces the catheter unit 101 deeper into blood vessel applying the needle 116 as a guide. As a result, the catheter unit 101 reaches the position with a definite distance from the needle assembly 102 (see FIG. 11). Further propelling the securing member 124 in distal direction by user's finger leads to the pressure of the actuating member 131 onto the protruding trigger member 122. As a result, the trigger member 122 moves downward releasing the spring 120, which automatically disconnects the catheter unit 101 from the needle 116 and introduces the needle distal sharp point 117 into the security zone 114 as it is shown in FIG. 12. In this case, the actuating means operates as an automatically starting actuating means. Thus, all the process of said disconnection is carried out by one hand of the user. Demanded distance between the catheter unit 101 and the needle assembly 102 before their disconnection is determined and strictly maintained owing to the definite given disposition of the actuating member 131 relatively the securing member 124. The triggering off said disconnection is effected automatically in required time without any pressure onto the start trigger button. The presence of the tight gasket 133 in the flash chamber 132 excludes the blood leakage from the flash chamber 132 for propelling the catheter 103 into blood vessel. The vent diaphragm 137 allows the air freely to go out in this period thereby providing free inlet indicating blood into the flash chamber 132. Moreover, for the disconnection of the catheter unit 101 and the needle assembly 102 the small gap 135 allows rapid air outlet from the cavity of the handle 110 and thereby provides free moving the needle hub 119 in proximal direction. In version embodiment, the gap 135 is carried out as several grooves on the outer surface of the needle hub 119 (not shown).

After described automatic disconnection of the catheter unit 101 from the needle assembly 102, the user removes the securing member 124 from the guide grooves 126 of the handle 110 and rotates the securing member 124 into opposite position as it is shown in FIG. 15. In

this position, the securing member 124 is applied as a attachment member which is compressed to the patient's body and enables to make stronger attachment of the catheter unit 101 to the patient's body.

The propelling means includes a plurality of the projections 127 located on the securing member 124 which is connected with the catheter unit 101 and movable with respect to the needle unit 115 so that at least part of the propelled projections are disposed within reach of the fingers of user's hand which holds the apparatus at its handle 110. Moreover, this part of the propelled projections 127 is always supported by the handle 110. Therefore, unlike US Patent 6056726, the present propelling means enables to operate the apparatus only by one user's hand and does not causes the increased friction or jams in a needle unit drive. All the advantages of the present trigger member (latch) in comparison with the prior art noted in the previous version embodiment relates to the present version too. Moreover, it should be noted that the securing member 124 connected with the catheter hub 107 plays a role of the obligatory means (in US Patent 6056726 it is called as self-contained coupling means) designed to prevent the disconnection of the needle assembly 102 from the catheter unit 101 until the needle unit 115 is displacement into the protected position. In the present version it does not create the transverse load onto the needle and consequently is prevented from the disadvantages noted for the prior art.

In version embodiment, the apparatus shown in FIG. 7 to 15 is carried out with the moving flash chamber 28 shown in FIG. 1 to 6 (this version embodiment is not shown). The version embodiment of the catheter insertion apparatus shown in FIG. 16 to 23 has the designations of the details with first numeral 2. The description of the previous version relates to the part of present version details with identical second and third numerals. At the same time, the present version has some distinctions, which mainly consist in the construction of the securing member 224. This member is made as a separate detail slidably mounted in the guide grooves 226 of the handle 210 and has a functional connection 240 with the catheter hub 207. This connection presents the contact between a distal edge 241 of the securing member 224 and a ledge 242 of the catheter hub 207. After introducing the needle distal sharp point 217 into patient's vein, the user propels the projections 227 in distal direction. As a result, the distal edge 241 of the securing member 224 abuts against the ledge 242 and displaces the catheter unit 201 in distal direction up to the trigger ready position of the trigger means thereafter the automatically starting actuating means operates: actuating member 231 displaces the trigger member 222 downward and the spring 220 disconnects the

catheter unit 201 from the needle assembly 202 as it is shown in FIG. 20. After that, there is no problem to disconnect the securing member 224 from the ledge 242 because they have only contact tie. Thus, the present version (FIG. 16 to 23) provides easy disconnection of the catheter hub 207 from the securing member 224 in the apparatus with the automatically starting actuating means. This is its main distinction and advantage in comparison with the previous version according to FIG. 7 to 15. Moreover, it enables to provide the automatic triggering off with minimal complication of the catheter hub 207.

In version embodiment (not shown), the securing member 224 having functional connection with the catheter hub 207 shown in FIG. 16 to 23 is applied in the apparatus with the movable flash chamber 28 shown in FIG. 1 to 6.

The version embodiment of the catheter insertion apparatus shown in FIG. 24 to 33 has the designations of the details with first numeral 3. The description of the previous versions relates to the details of the present version with identical second and third numerals. The present version comprises the securing member 324 connected with the catheter unit 301 by means of flexible pivotable member 330. Such connection has as well the version shown above in FIG. 7 to 15. However, as distinct from FIG.7 to 15 the present version has the trigger start beginning means 321 with a manual control by means of a button 325. The present version comprises as well the obligatory securing means, which prevents the disconnection of the needle assembly 302 from the catheter unit 301 until the needle unit 315 is displaced to the protected position. Said obligatory securing means includes the button 325 and a stopping member 344 made as a single unit with the securing member 324. After introducing the needle distal sharp point 317 into patient's vein and the appearance of the blood in the movable flash chamber 328, which is described in the version according to FIG. 1 to 6, the user propels the projections 327 in distal direction. As a result, the securing member 324 and the catheter unit 301 are displaced in distal direction with respect to the needle unit 315 until the button 325 gets into a window in the stopping member 344 (see FIG. 30). In this moment, the button 325 blocks as a latch further displacement of the catheter unit 301 in distal direction preventing the disconnection of the needle assembly 302 from the catheter unit 301. To disconnect them, the user presses the button 325 displacing it downward (see FIG. 31). As a result, the trigger member 322 releases the spring 320 and the spring 320 transposes the needle unit 315 into protected position (see FIG. 31). Simultaneously, the displacement of the button 325 downward releases the securing member 324 and allows complete disconnection of the catheter unit 301 from the needle assembly

302 (see FIG. 32, 33). Unlike the version with the obligatory securing means and automatic controlled trigger means, shown in FIG. 7 to 15, the present version provides said obligatory securing means in the embodiment with manual controlled triggering means.

Moreover, the present version (FIG. 24 to 33) includes unidirectional needle motion means for the prevention of the needle return movement distally to the catheter after the needle removal out of the catheter has begun. Said unidirectional needle motion means includes the toothed engagement members 343 situated on the handle 310 and interacting with the distal edge 345 of the securing member 324 (see FIG. 25, 26, 28, 29, 30, 32). After beginning the movement of the securing member 324 and the catheter unit 301 in the distal direction with respect to the needle assembly 302, the members 343 and 345 rule out the possibility of the return movement and thereby prevent the catheter tube 303 from the injury by the needle sharp point 317.

In version embodiment (not shown), the apparatus shown in FIG. 16 to 23 are as well provided with such unidirectional needle motion means with interacting toothed engagement members 343 and the edge 345 shown in FIG. 25 to 32.

The version embodiment of the catheter insertion apparatus shown in FIG. 34 to 41 has the designations of the details with first numeral 4. The description of the previous versions relates as well to the details of the present version with identical second and third numerals. At the same time, the present version has several substantial distinctions described below. The apparatus includes the catheter unit 401 and the needle assembly 402. The latter has the guard member 450 consisting of a distal 446 and a proximal 447 immovably joined parts. The distal part 446 comprises the needle guard means 412 and the propelling means with the projections 427 made as a single unit. The guard member 450 slidably houses the handle 449 with the gripping members 448 which are used by the user for holding the apparatus. The trigger means includes the latch 422 mounted in the handle 449. These handle 449 and latch 422 are movable with respect to each other and to the needle guard means 412. The lath 422 is as well movable with respect to the needle unit 415, unlike the prior art. The trigger means is automatic controlled by means of the actuating member 431 located on internal surface of the guard member 450. After introducing the distal sharp point 417 into patient's vein and appearance of the blood in the movable flash chamber 428, the user, which holds the apparatus at the gripping members 448, propels the projections 427 in distal direction. As a result, the guard member 450 along with the needle guard means 412 and the catheter unit 401 are transposed in distal direction with respect to the handle 449 and the needle 416 until

the actuating member 431 is emplaced in the trigger ready position shown in FIG. 39. For this transposition, the latch 422 does not create substantial friction impeding said transposal or hampering the user's sense of the resistance of patient's body. Further displacement of the actuating member 431 in distal direction leads to the displacement of the latch 422 downward and releasing the spring 420. The released spring 420 propels the needle hub 419 up to an abutment against proximal inner face of guard member proximal part 447 and simultaneously introduces of the needle distal sharp point 417 into the security zone 414 (see FIG. 40). After that, without an interruption, the spring 420 transposes the guard member 450 and all needle assembly 402 to the position of complete disconnection of the needle assembly 402 from the catheter unit 401 (see FIG. 41). Thus, this version provides two important advantages: 1) rules out the withdrawal non-guarded needle distal sharp point 417 from the catheter unit 401 owing to the observance of strict succession of automatic operations: first introducing the needle distal sharp point 417 into the security zone 414 and only then the disconnection of the catheter unit 401 from the needle assembly 402; 2) provides automatic complete disconnection of the catheter unit 401 and the needle assembly 402.

The version embodiment of the catheter insertion apparatus shown in FIG. 42 to 49 has the designations of the details with first numeral 5. The description of the previous version shown in FIG. 34 to 41 relates to the majority of the present version details with identical second and third numerals because they relate mainly to the same type of the apparatus. The distinction of the present version consists only in the indirect manual controlled triggering means. This means includes the manual actuating member 551 made as an integral part of the guard member 550 and connected with it by means of flexible pivotable member 552. This version has the face 553 on the handle 549 and proximal face 554 of the slot in the guard member 550 which provide the required given distance between the catheter unit 501 and needle unit 515 immediately before triggering off the needle unit movement into the protected position. After introducing the needle distal sharp point 517 into patient's vein, the user propels the projections 527 and along with it the guard member 550 and the catheter unit 501 in distal direction with respect to the handle 549 and the needle 516 until the face 554 abuts against the face 553. In this last position (see FIG. 47), the required distance between the catheter unit 501 and the needle unit 515 is provided and mutual disposition of the trigger member 522 and the actuating member 551 enables to trigger off the needle unit 515 movement into the protected position. The user presses the actuating member 551

displacing the trigger member 522 downward and thereby releasing the spring 520. As a result, the spring 520 transposes the needle unit 515 into the protected position (see FIG. 48) and, immediately after that, disconnects automatically the needle assembly 502 from the catheter unit 501 (see FIG. 49). The present version embodiment (FIG. 42 to 49) provides the same advantages, which were noted for the previous version (see FIG. 34 to 41). Moreover, the present version, as distinct from said previous one, enables the user consciously to choose the instant of the triggering off the needle unit movement into the protected position and to prepare himself for this instant:

The version embodiment of the catheter insertion apparatus shown in FIG. 50 to 56 has the designations of the details with first numeral 6. The description of the previous versions relates to the part of the present version details with identical second and third numerals. However, the present version has a few substantial distinctions, which are described below. This version has shortened handle 610 with applying an expandable sleeve 655 in particular in the form of belows interconnecting the handle 610 and the flash chamber 628 made as an integral part of the needle hub 619. This enables substantially to shorten the handle 610 and the apparatus as a whole in its initial expanded position. Moreover, the apparatus is provided with the trigger member made as a latch 622 with a manual actuated springy button 656. This trigger means has three positions: initial locking position (see FIG. 52), release position (not shown) and shielding position (see FIG. 55), wherein the trigger member 622 plays a role of a shied member preventing the needle distal sharp point 617 from going out in distal direction. After introducing the needle sharp point 617 into patient's vein, the user displaces the catheter unit 601 in distal direction for a demanded distance from the needle assembly 602 (see FIG. 54). Then, the user presses the button 656 and thereby displaces the trigger member 622 downward into the releasing position releasing thereby the spring 620. As a result, the spring 620 transposes the needle unit 615 in extreme proximal position expanding the sleeve 655 as it is shown in FIG. 55, 56. After releasing the button 656 by user, the trigger member 622 goes up to the shield position (see FIG. 55) owing to the springy properties of the button 655. As a result, the trigger member 622 acts as a shield preventing the needle distal sharp point 617 from going out in distal direction. Such shield is necessary because of insufficient rigidity of the expandable sleeve 655. The expanded sleeve fulfils the role of a retaining means preventing the distal sharp point 617 from going out of the protected position in proximal direction. The advantage of the present version is shortening

the length of the apparatus in initial state. This decreases the transport expenses and material consumption.

The version embodiment shown in FIG. 57 to 68 has the designations of the details with first numeral 7. The description of the previous version (FIG. 50 to 56) relates to the details of the present version with identical second and third numerals. The present and previous versions relate to the same type of the apparatus with shortened handle 610, 710 and have the same advantages noted above for the previous version. However, the present version comprises a lot of additional means considered below. The mentioned additional means include the securing member 724 having the propelled projections 727 and removable functional connection with the catheter hub 707, comprising the axle 759, engagement member 758 and limiter 757. The securing means rules out the possibility of accidental actuating the trigger member 722 and provides strict observance of the required distance between the catheter unit 701 and the needle unit 715 at the moment of the trigger means actuating (see FIG. 61). The apparatus of the present version comprises the obligatory means ruling out the disconnection of the catheter unit 701 from the needle assembly 702 until the needle unit 715 is displaced into the protected position shown in FIG. 62. The obligatory means includes the engagement member 758 and the limiter 757 impeding said disconnection. There is as well an automatic control of the trigger means by the actuating member 731 interacting with the trigger means springy button 756. Moreover, the securing member 724 can be applied as a attachment member for stronger attachment of the catheter hub 707 to the patient's body as it was described for the version embodiment according to FIG. 7 to 14 and FIG. 24 to 33. However, as distinct from said versions, the present version enables to disconnect the securing member 724 and the catheter hub 707 without effort if it is necessary (see FIG. 68). After introducing the needle distal sharp point 717 into patient's vein, the user propels the projections 727 in the distal direction and thereby displaces the securing member 724 and the catheter unit 701 as a whole into a position shown in FIG. 61. Further distal displacement of the securing member 724 by user leads to the automatic displacement of the trigger member 722 downward by the actuating member 731 and releasing the spring 720. As a result, the latter automatically transposes the needle unit 715 into the protected position shown in FIG. 62, 63. Further displacement of the securing member 724 distally leads to complete disconnection of the catheter unit 701 from the needle assembly 702 as it is shown in FIG. 64. In this disconnected position, the trigger member 722 goes up to the shield position (see FIG. 64) under the action of the springy button 756. The trigger member 722 in said shield

position plays the role of the shield impeding going out the needle distal sharp point 717 in distal direction. Thus, the present version (FIG. 57 to 67) enables to join in the unit apparatus the shortened handle with the means providing effective security properties.

The version embodiment shown in FIG. 69 to 76 has the designations of the details with first numeral 8. The description of the previous versions relates to the details of the present version with identical second and third numerals. The present version distinguishes substantially from all previous embodiments first of all by the absence of the spring because the movement of the needle unit 815 into the protected position is effected manually. Another important distinction of the present invention is the engagement of the needle assembly 802 and the catheter unit 801 located inside the catheter hub 807. This engagement is provided with an anchor means, which includes protrusions 866 located on distal end of resilient fingers 865 of a guard member 861 and recesses 867 inside the catheter hub 807. In engaging position, the protrusions 866 are disposed inside the recesses 867 and are locked there by means of spreader sleeve 812 receiving the needle 616. The needle hub 819 is made as a single unit with gripping parts 848 and the flash chamber 828 and movably mounted in the guard member 861. The latter is provided with the propelled projections 827. The apparatus comprises as well a locking means for locking the needle unit 815 in the protected position. Said locking means includes the locking members in form of the ridges 862 located on the proximal end of the guard member 861 and the ridges 863, 864 located on internal surface of the proximal part of the gripping parts 848. Moreover, the apparatus includes the obligatory securing means preventing the disconnection of the catheter hub 801 from the needle assembly 802 until the needle unit 815 gets in the protected position. Said obligatory securing means includes above mentioned protrusions 866, the recesses 867, the spreader sleeve 812 as well as a control rod 868 for the control of the position of the spreader sleeve 812. The channel inside the spreader sleeve 812 is the security zone 814 containing the needle distal sharp point 817 in its protected position. The user holds the apparatus at its gripping parts 848 and sticks the needle distal sharp point 817 into patient's vein. Then, the user propels the projections 827 in distal direction introducing the catheter tube 803 deeper into patient's body until the proximal edge of the plug 829 abuts against an engagement member 869 (see FIG. 74). As a result of further propelling the projections 827 in distal direction, the plug 829 pushes the engagement member 869 and thereby the control rod 868 in proximal direction and the latter displaces the spreader sleeve 812 in proximal direction (see FIG. 75). Obtained position is the protected position of the needle unit 815. Said

displacement of the spreader sleeve 812 enables the resilient fingers 865 to flex inward and thereby to release the engagement of the protrusion 866 and the recesses 867 (see FIG. 76). As a result, the disconnection of the catheter unit 801 from the needle assembly 802 is effected. The application of the spreader sleeve 812 increases the disconnecting transverse stroke of the protrusions 866. That enables to make the protrusions 866 and the recesses 867 sufficiently great to provide their reliable operation. This is especially important for the needle 816 of small diameter. The ridges 862 (see FIG. 69) of the locking means in the protected position (see FIG. 74, 75) are disposed between the locking members 863 and 864, which prevent the significant displacement of the needle unit 815 in distal or proximal direction and thereby retain reliably the needle unit 815 in its protected position. The version embodiment shown in FIG. 77 to 84 has the designations of the details with first numeral 9. The description of the previous version (see FIG. 69 to 76) relates to the details of the present version with identical second and third numerals. Both versions relate to the same type of the apparatus. There is only one substantial distinction between them: the apparatus according to FIG. 69 to 76 is designed preferably for the application of the thin needle 816 and therefore is provided with the spreader sleeve 812 and control rod 868 and the apparatus according to FIG. 77 to 84 is designed preferably for thick needles 916 and there is no need in said details there.

The peculiarity and the advantage of these version embodiments (FIG. 69 to 76 and 77 to 84) in comparison with the prior art is the position of the resilient fingers 865, 965 which in their natural state even without the needle 816, 916 are pressed onto the recesses 867, 967 by their protrusions 866,966 and have open security zone 814,914 (see 74, 82). This facilitates the assembly of the apparatus and rules out premature spontaneous disconnection of the catheter unit 801, 901 from the needle assembly 802,902 in the initial stage of the introduction of the distal sharp point 817,917 into the security zone 814,914 respectively. Another peculiarity of the version embodiment shown in FIG. 77 to 84 is the presence only one resilient finger 965 adjacent to the needle distal sharp point 917 (see FIG. 82 to 84). This as well rules out mentioned premature spontaneous disconnection of the catheter unit 901 from the needle assembly 902 because the resilient finger 965 is ready for bending and the disconnection only after the displacement of the distal sharp point 917 into the position near to final protected position (see FIG. 84). The upper finger 970 is released earlier however it is not resilient.

The version embodiment of the apparatus shown in FIG. 85 to 90 has the designations of the details with first two numerals 10. The descriptions of the previous versions according to FIG. 69 to 76 and FIG. 77 to 84 relate to the details of the present version with identical two last numerals. All the three versions relate to the same type of the apparatus. The peculiarity of the present version lies in its twist lock means engaging the guard member 1061 with the catheter unit 1001. Said twist lock means include a standard twin-screw thread 1039 on the catheter hub 1007 and said thread 1072 on the guard member 1061. This is the standard thread conventionally applied in the catheter hubs and demanding only half revolution for the connection of the catheter unit 1001 and the needle assembly 1002. Said twist lock means are provided with a detent means which includes a longitudinal recess 1073 in the catheter hub 1007 and detent rod 1068 placed into the guard member 1061 and having a shaft 1074, a shaft engagement member 1069 and a distal detent end 1071 which is disposed in the longitudinal recess 1073 in the extended position of the needle unit 1015 shown in FIG. 89, 90. Said detent means prevents the rotation of the guard member 1061 with respect to the catheter hub 1007 and thereby prevents their disconnection. After introducing the needle distal sharp point 1017 into patient's vein, the user propels the projection 1027 and the guard member 1061 as a whole in distal direction until the plug 1029 abuts against the shaft engagement member 1069. At the moment, the needle unit 1015 is in the protected position (see FIG.85). Further movement of the guard member 1061 in distal direction leads to the displacement of the detent rod 1068 in proximal direction and as a result the withdrawal of the distal detent end 1017 from the longitudinal recess 1073 (see FIG. 86, 87). This enables to disconnect the catheter unit 1001 from the needle assembly 1002 by rotation them with respect to each other by half revolution. The needle unit 1015 in its final protected position (see FIG. 86) is fixed by locking member 1062, 1063, 1064.



What we claim is:

- 1. A catheter insertion apparatus comprising:
 - a catheter unit having a catheter with a distal end, a proximal end, an open passageway therethrough, and a catheter hub affixed to the said catheter proximal end;
 - a needle assembly having:
 - a proximal end and a distal end adjacent to which said catheter hub being releasably connected;
 - a handle with an open bore therethrough;
 - a needle guard means, having sharp point guard with security zone;
 - a needle unit, having a tubular needle with sharp distal point, a proximal end and
 - a needle hub affixed to said proximal needle end, said needle having extended position wherein said needle is disposed within said handle and through said open bore into said catheter passageway so that said distal sharp point of said needle projects axially beyond said distal end of said catheter, so that being in said extended position said needle is in distal position with respect to said sharp point guard wherein said sharp distal point is in maximal remote position from said sharp point guard;
 - a spring interacting with said needle hub to urge said needle unit to a protected position wherein, said needle sharp distal point is permanently retained within said security zone so that any accidental contact with said sharp distal point is precluded;
 - a trigger means, having a trigger member associated with said handle and having a locking position in which it retains said needle unit in a distal position relative to said handle, and a release position in which it releases said needle; said trigger member is movable with respect to said needle unit when said trigger member is displaced from said locking position into said release position;
- a trigger securing means for preventing unconscious starting said trigger means and having a securing member slidably located on exterior upper surface of said handle, controlled by the same user's hand which holds the apparatus, and having a start trigger prevention position, wherein said trigger means start is impossible, and a start trigger ready position, wherein said trigger means are ready to be activated.

- 2. The catheter insertion apparatus of claim 1, wherein there is obligatory securing means that prevents disconnection of said needle assembly from said catheter unit before said needle unit is displaced to said protected position.
- 3. The catheter insertion apparatus of claim 1, wherein there is trigger start beginning defining means for the prevention of unconscious starting said trigger means before said needle unit is displaced from said catheter unit to a definite given distance.
- 4. The catheter insertion apparatus of claim 1, wherein there is unidirectional needle motion means allowing said needle unit displacement only proximally with respect to said catheter unit.
- The catheter insertion apparatus of claim 1, wherein there is a propelling means making functional interaction of said catheter unit with said needle unit and adapted to the displacement of said catheter unit in the inserting direction distally with respect to said needle unit, and/or for fixing said catheter unit in a blood vessel upon withdrawing said needle unit out of said catheter unit and disconnection of said needle assembly from said catheter unit; said propelling means has a propelling member slidably located on exterior upper surface of said handle, movable with respect to said needle unit, adapted to the transmission of pushing efforts to said catheter unit from the finger of the same user's hand which holds the apparatus, therewith said pushing efforts are applied to the portion of said propelling member disposed in zone of said handle and supported immediately from below by said handle.
- 6. The catheter insertion apparatus of claim 1, wherein there is an attachment means for fixing said catheter unit to a patient skin, and having an attachment member situated on said catheter hub.
- 7. The catheter insertion apparatus of claim 1, having stopping means for stopping said securing member in said start ready position.

- 8. The catheter insertion apparatus of claim 1, wherein said trigger means has at least one directly operated trigger member adapted for direct operation by users' fingers outside the handle.
- 9. The catheter insertion apparatus of claim 1, wherein said securing member has distal end by which it is functionally connected with said catheter hub.
- 10. The catheter insertion apparatus of claim 2, 7, 8, 9, wherein said stopping means is controlled by said trigger member, stops said securing member in said start ready position, and prevents further withdrawal of said needle unit out of said catheter unit so that the continuation of said withdrawal and further disconnection of said needle assembly from said catheter unit is possible only after said trigger means starting.
- 11. The catheter insertion apparatus of claim 8, wherein said securing member is made as a screen, which in said start trigger prevention position hampers direct approach of user's fingers to said trigger member and allows said direct approach, being moved to said start trigger ready position.
- 12. The catheter insertion apparatus of claim 10, in further combination with claim 11.
- 13. The catheter insertion apparatus of claim 8, wherein said securing member is made as a securing lock member, which in said start trigger prevention position locks said trigger member, precluding said trigger means start and unlocks said trigger member, being transferred to said start trigger ready position.
- 14. The catheter insertion apparatus of claim 10, in further combination with claim 13.
- 15. The catheter insertion apparatus of claim 1, wherein there is an actuating means for mediate control of said trigger means and having at least one actuating member movable with respect to said trigger means at least between the idle position, when said actuating member is situated apart from said trigger means and proximally of it, and trigger position, when said actuating member is situated in the immediate vicinity of

said trigger means so that actuating motion applied to said actuating member results in said trigger means start.

- 16. The catheter insertion apparatus of claim15, wherein said actuating means is made as an automatically starting actuating means, so that said actuating motion results from the continuation of said displacement of said actuating member from said idle position to said trigger position.
- 17. The catheter insertion apparatus of claim 2, 9,16, wherein said obligatory securing means comprises said actuating means made as obligatory automatically starting actuating means, having said securing member and said actuating member functionally connected together and to said catheter unit at least until said trigger means start as a consequence of estranging displacement of said catheter unit from said handle in distal direction or said handle from said catheter unit in proximal direction.
- 18. The catheter insertion apparatus of claim1 wherein:
- said handle and said guard means are made integral and having a longitudinal cavity communicated to said open bore;
- a flash chamber located within said longitudinal cavity;
- said trigger member made as a latch;
- said needle hub placed into said longitudinal cavity in its distal part when said needle unit is in said distal position, and said needle placed in rearward position, which is simultaneously said protected position when said needle hub is placed in proximal part of said cavity and said needle unit is retained in said rearward position by said spring.
- 19. The catheter insertion apparatus of claims 3, 4, 5, 6, 17, 18, wherein
- said securing member and said actuating member are made integral as a single part slidably mounted in the guides on said handle;
- said securing member operates as said propelling means and has a plurality of projections located on upper surface;
- said distal end of said securing member is pivotably connected to said catheter hub and after total disconnection of said catheter unit from said needle assembly said

securing member pivots by appr. 180° around the point of its mounting to said catheter hub and is used as said attachment means for fixing said catheter unit on a patient skin;

- said actuating member is made as a cam adapted to moving said latch from locking position to release position;
- said actuating member is situated at a predetermined distance from said catheter hub
 in said extended position and operates as said trigger start beginning defining means,
 since trigger means start begins when said catheter unit is removed from said needle
 unit by said predetermined distance;
- said one unidirectional needle motion means, having interacting engagement members situated on said securing member and said handle along said needle assembly longitudinal axis and made, for instance as toothed members on said handle and as proximal edge of said securing member, to prevent return displacement of said needle unit in distal direction with respect to said catheter unit after the beginning of said needle unit moving from said extended position.
- The catheter insertion apparatus of claim 18, in further combination with claim 3, 4, 5, 14.
- 21. The catheter insertion apparatus of claim 18, in further combination with claim 12.
- 22. The catheter insertion apparatus of claim5, 7, 15 wherein:
- said guard means having hollow elongated guard member comprising said sharp point guard, slidably located within said handle, and by its distal end, which is at the same time said needle assembly distal end, removably attached to said catheter hub;
- said handle having gripping parts placed outside of said guard member and bilaterally of it, and a handle base placed inside of said guard member;
- said gripping parts and said handle base joined together by at least one dam passing through limiting slot in the wall of said guard member and said stopping means includes said dam and a distal edge of said limiting slot;
- said needle unit having a flash chamber connected to said needle hub;
- said trigger member made as a latch.

- said actuating member made as a pusher placed on said guard member and adapted,
 upon being pressed on, to displace said latch from said locking position to said release position;
- said needle hub placed in said longitudinal cavity in its distal part when said needle
 unit is in said distal position, and in said rearward position (which also serves as said
 protected position) said needle hub is placed in proximal part of said cavity and said
 needle unit is retained in said position by said spring.
- in said distal position said needle unit is attached to said handle base and together they are movable along said guard member within said limiting slot in said wall of said guard member between said start trigger prevention position and said start trigger ready position in which, upon pressing said actuating member, said latch releases said needle unit and said spring based on said handle base moves said needle unit in proximal direction relatively said guard member to said protected position, and reaching it, said spring moves said guard member and said needle unit together proximally relative to said handle until said guard member reaches extreme proximal position relative to said handle and is held in this position by said spring.
- 23. The catheter insertion apparatus of claim 3, 5, 17, wherein:
- said handle and said guard means are made integral;
- said spring is a coil spring coaxially disposed about said needle and compressed between said needle hub and said handle;
- said trigger member is made as a latch, having a shield part spring-backed to said
 handle so that after said needle unit displacement to said protected position, said shield
 part shifts to shielding position and thus prevents said sharp distal point displacement
 beyond the bounds of said security zone in distal direction;
- there is a restraining means preventing said sharp distal point from displacing beyond the bounds of said security zone in proximal direction and said restraining means are made as expandable sleeve interconnecting said handle and said needle hub and placed on the outside said spring;
- said securing member and said actuating member are made as an integral part slidably mounted in the guides on said handle;
- said actuating member is made as a cam adapted to moving said latch from locking position to release position;

- said distal end of said securing member is mounted to said catheter hub;
- said securing member operates as said propelling means, and for that it has a
 plurality of projections located on its upper surface;
- a flash chamber located in said needle hub.
- 24. A catheter insertion apparatus comprising:
- a catheter unit, having a catheter, having a distal end, a proximal end, an open passageway there through, and a catheter hub affixed to the said catheter proximal end;
- a needle assembly having:
- a proximal end and a distal end adjacent to which said catheter hub being releasably connected;
 - handle with an open bore there through;
 - needle guard means, having a sharp point guard with a security zone;
 - a needle unit, having a tubular needle, having a sharp distal point, a proximal end, and a needle hub affixed to said proximal needle end, said needle having an extended position, wherein said needle is disposed within said handle and passing through said open bore into said catheter passageway so that said sharp distal point of said needle projects axially beyond said distal end of said catheter, said needle is in distal position relative to said sharp point guard, and said sharp distal point is maximally remote from said sharp point guard, and a protected position, wherein said sharp distal point is located in said security zone;
 - an obligatory securing means having an obligatory securing member movable in axial direction relative to said needle, providing the possibility of the disconnection of said catheter unit and needle assembly not early than said needle is transposed into said protected position, and adapted to control by the same one user's hand which holds the apparatus using a propelling means; said propelling means has a propelling member slidably located on exterior upper surface of said handle, movable with respect to said needle unit, adapted to the transmission of pushing efforts to said catheter unit from the finger of said user's hand, therewith said pushing efforts are applied to the portion of said propelling member disposed in zone of said handle and supported immediately from below by said handle.

25. The catheter insertion apparatus of claim 24, wherein said obligatory securing member is movably located in a guide on exterior upper surface of said handle and secured to said catheter unit so that said disconnection of catheter unit and needle assembly is possible only as a result of complete coming out said securing member from said guide in distal direction occurring not early than said needle is transposed into said protected position.

the first of the second of the

- 26. The catheter insertion apparatus of claim 25 wherein:
- said handle and said guard means are made integral and having a longitudinal cavity communicated to said open bore;
- a flash chamber is located within said longitudinal cavity;
- said needle hub is placed in said longitudinal cavity in its distal part when said needle unit is in said distal position, and said needle is placed in rearward position, which is simultaneously said protected position when said needle hub is placed in proximal part of said cavity.
- 27. The catheter insertion apparatus of claim 25, wherein there is a trigger start beginning defining means for preventing said trigger means from unconscious starting before said needle unit is displaced from said catheter unit to a definite given distance.

The transfer as the public to express the property of

- 28. The catheter insertion apparatus of claim 25, wherein said propelling means makes functional interaction of said catheter unit with said needle unit and adapted to the displacement of said catheter unit in the inserting direction distally with respect to said needle unit, and/or for fixing said catheter unit in a blood vessel upon withdrawing said needle unit out of said catheter unit and said disconnection of said needle assembly from said catheter unit; and said propelling member and said obligatory securing member are made as an integral part.
- 29. The catheter insertion apparatus of claim 26, wherein: said flash chamber is made as a movable flash chamber made as a hollow member mounted on said proximal end of said needle in-fluid communication with needle passage and having air communicating opening covered by vent diaphragm formed of gas-only permeable material, whereby liquid may not pass therethrough.

30. The catheter insertion apparatus of claims 25, 26, 27, 28 wherein there are:

a spring interacting with said needle hub to urge said needle unit to said protected position wherein at least said needle sharp distal point is permanently retained within said security zone so that any accidental contact with said sharp distal point is precluded;

a trigger means, having a trigger member associated with said handle and having a locking position in which it retains said needle unit in distal position relative to said handle and a releasing position in which it releases said needle unit;

a trigger securing means for preventing said trigger means from unconsciously starting, using said obligatory securing member with a start trigger prevention position, wherein said trigger means start is impossible, and a start trigger ready position, wherein said trigger means are ready to be manually activated;

said obligatory securing member having a distal end by which it is functionally connected with said catheter hub;

said obligatory securing member made as a screen, which in said start trigger prevention position hampers direct approach of user's fingers to said trigger member;

an actuating means for mediate control of said trigger means having at least one actuating member movable with respect to said trigger means at least between the idle position, when said actuating member is situated apart from said trigger means and proximally of it, and the trigger position, when said actuating member is situated in the immediate vicinity of said trigger means so that actuating motion applied to said actuating member results in said trigger means starting;

said actuating means made as an automatically starting actuating means so that said actuating motion results from the continuation of said displacement of said actuating member from said idle position to said trigger position.

said obligatory securing means comprising said actuating means made as obligatory automatically starting actuating means, having said obligatory securing member and said actuating member functionally connected together and to said catheter unit at least until said trigger means start as a consequence of the displacement of said catheter unit from said handle in distal direction or said handle from said catheter unit in proximal direction;

said trigger member made as a latch;

- said needle unit retained in said rearward position by said spring;
- said obligatory securing member and said actuating member made integral as a single part slidably mounted in said guide on said handle;
- said obligatory securing member operating as said propelling means and having a plurality of projections located on its upper surface;
- said actuating member made as a cam adapted to moving said latch from said locking position to said releasing position;
- hub in said extended position and operating as a trigger start beginning defining means, since trigger means start begins when said catheter unit is removed from said needle unit by said predetermined distance.
- 31. The catheter insertion apparatus of claim 24, wherein said obligatory securing member includes anchor means on it distal end for engagement of said obligatory securing member with said catheter unit and a block member blocking the connection of said catheter hub and anchor means and unblocking said connection not earlier than said needle is transposed into said protected position.

The same continue and

- 32. The catheter insertion apparatus of claim 31, wherein:
 said block member has a rigid finger located on the sloping side of said needle and said
 anchor means has at least one resilient finger with a protrusion on its distal end and a
 corresponding recess in said catheter hub, said resilient finger is adapted to flex radially
 to permit said finger to enter said catheter hub and return to the rest position to engage
 said catheter hub when said protrusion is set on the level of said recess, therewith said
 resilient finger is placed on said needle distal end opposite to sloping side of said needle
 distal end, and the noted arrangement of said resilient and rigid fingers ensures going
 out said protrusion from said recess and thereby the disconnection of said needle unit
 from said catheter unit only after said protrusion is displaced distally of said distal sharp
 point and said needle unit is got into said protected position.
- 33. The catheter insertion apparatus of claim 31, wherein:
 - said anchor means has at least two resilient fingers with a protrusion on its distal end and a corresponding recess in said catheter hub, said fingers are placed on

said distal end of said guard member and being adapted to flex radially to permit said fingers to enter said catheter hub and return to the rest position to engage said catheter hub when said protrusion is set on the level of said recess;

- said block member has a control rod and a spreader sleeve connected to said control rod and located between said needle and said fingers to prevent said at least two resilient fingers from inward radial flexing and disconnecting of said obligatory securing means from said catheter unit before said spreader sleeve is displaced by said control rod proximally relative to said protrusion as a result of said withdrawing motion of said needle unit out of said catheter unit and the noted arrangement of said block member and resilient fingers ensures going out said protrusion from said recess and thereby disconnection of said needle unit from said catheter unit only after said protrusion is located distally of said distal sharp point and when said needle unit is into said protected position.
- 34. The catheter insertion apparatus of claim 31, wherein said anchor means is made as a twist lock means engaging said obligatory securing member to said catheter hub and said block member includes a shaft having a distal detent end and a proximal shaft engagement member; said detent end is entering a longitudinal recess in said catheter hub in said extended position to prevent said obligatory securing member from rotating relative to said catheter hub thereby preventing said needle unit from disconnecting from said catheter unit until said distal detent end is withdrawn from said longitudinal recess by said needle hub via said shaft and shaft engagement member as a result of withdrawing motion of said needle unit out of said catheter unit into said protected position.

35. A catheter insertion apparatus comprising:

- a catheter unit, having a catheter, having a distal end, a proximal end, an open passageway therethrough and a catheter hub affixed to the said catheter proximal end;
- a needle assembly having:
- a proximal end and a distal end adjacent to which said catheter hub being releasably connected;
- a handle with an open bore therethroung;
- a needle guard means, having a sharp point guard with a security zone;

a needle unit, having a tubular needle, having a sharp distal point, a proximal end and a needle hub affixed to said proximal needle end, said needle having an extended position, wherein said needle is disposed within said handle and passing through said open bore into said catheter passageway so that said distal point of said needle projects axially beyond said distal end of said catheter so that, being in said extended position, said needle is in distal position relative to said sharp point guard, wherein said sharp distal point is maximally estranged from said sharp point guard;

a flash chamber: A market of the part was a second of the control of the specific way.

a propelling member making functional interaction of said catheter unit with said needle unit and adapted to the displacement of said catheter unit in the inserting direction distally with respect to said needle unit, and/or for fixing said catheter unit in a blood vessel upon withdrawing said needle unit out of said catheter unit and disconnection of said needle assembly from said catheter unit, said propelling member slidably located on exterior upper surface of said handle, movable with respect to said needle unit, adapted to the transmission of pushing efforts to said catheter unit from the finger of the same user's hand which holds the apparatus, therewith said pushing efforts are applied to the portion of said propelling member disposed in zone of said handle and supported immediately from below by said handle;

an unidirectional needle motion means allowing said needle unit displacement only proximally with respect to said catheter unit and including interacting engagement members of ratchet type located on said propelling member or the details connected with it and on said handle or the details connected with it and disposed beyond the interior of said flash chamber.

36. A catheter insertion apparatus of claim 35, wherein one of said interacting engagement members situated on said propelling member is a pawl and made as a proximal edge of said propelling member and another of said interacting engagement members situated on said handle are made as a plurality toothed members extended along the longitudinal axis of said needle assembly.

37. A catheter insertion apparatus of claim 36, wherein there are:

a spring interacting with said needle hub to urge said needle unit to a protected position wherein said needle sharp distal point is permanently retained within said security zone so that any accidental contact with said sharp distal point is precluded;

a trigger means, having trigger member associated with said handle and having locking position in which it retains said needle unit in distal position relative to said handle and releases said needle unit when being moved in release position;

a trigger securing means preventing unconscious starting said trigger means and having securing member with start trigger prevention position, wherein said trigger means start is impossible, and start trigger ready position, wherein said trigger means are ready being manually activated;

stopping means for stopping said securing member in said start ready position; said trigger means having at least one directly operated trigger member adapted for direct operation by users' fingers outside the handle;

said securing member having a distal end by which it is functionally connected with said catheter hub;

said stopping means controlled by said trigger member which stops said securing member in said start ready position and prevents further withdrawal of said needle unit out of said catheter unit so that the continuation of said withdrawal and further disconnection of said needle assembly from said catheter unit is possible only after said trigger means starting;

said securing member made as a securing lock member, which in said start trigger prevention position locks said trigger member, precluding said trigger means start and unlocks said trigger member, being transferred to said start trigger ready position;

said handle and said guard means made integral and having a longitudinal cavity communicated to said open bore;

a flash chamber connected with said needle hub;

said trigger member made as a latch;

said needle hub placed in said longitudinal cavity in its distal part when said needle unit is in said distal position, and said needle placed in rearward position, which is simultaneously said protected position, when said needle hub is placed in proximal part of said cavity and said needle unit is retained in said rearward position by said spring;

said securing member and said propelling member made integral, movably mounted in guide grooves of the said handle, and having a plurality of projections located on upper surface.

38. A catheter insertion apparatus comprising:

- a catheter unit having a catheter with a distal end, a proximal end, an open passageway therethrough, and a catheter hub affixed to the said catheter proximal end;
- □ a needle assembly having:
 - a proximal end and a distal end adjacent to which said catheter hub being releasably connected;
 - a handle with an open bore therethrough;
 - a needle guard means, having sharp point guard with security zone;
- a needle unit, having a tubular needle with sharp distal point, a proximal end and a needle hub affixed to said proximal needle end, said needle having an extended position, wherein said needle is disposed within said handle and passing through said open bore into said catheter passageway so that said distal point of said needle projects axially beyond said distal end of said catheter, and said needle is in distal position with respect to said sharp point guard wherein said sharp distal point is in maximal remote position from said sharp point guard;
- a spring interacting with said needle hub to urge said needle unit to a protected position wherein said needle sharp distal point is permanently retained within said security zone so that any accidental contact with said sharp distal point is precluded;
- a trigger means, having trigger member associated with said handle and having locking position in which it retains said needle unit in distal position relative to said handle and releases said needle unit when being moved in release position;
- a propelling means making functional interaction of said catheter unit with said needle unit and adapted to the displacement of said catheter unit in the inserting direction distally with respect to said needle unit, and/or for fixing said catheter unit in a blood vessel upon withdrawing said needle unit out of said catheter unit and disconnection of said needle assembly from said catheter unit; said propelling means has a propelling member slidably located on exterior upper surface of said handle, movable with respect to said needle unit, adapted to the transmission of pushing efforts to said catheter unit

from the finger of the same user's hand which holds the apparatus, therewith said pushing efforts are applied to the portion of said propelling member disposed in zone of said handle and supported immediately from below by said handle.

- 39. The catheter insertion apparatus of claim 38, having a trigger securing means for preventing said trigger means from unconscious starting and having a securing member with a start trigger prevention position, wherein said trigger means start is impossible, and a start trigger ready position, wherein said trigger means are ready to be manually activated.
- 40. The catheter insertion apparatus of claim 39, wherein there is an obligatory securing means that prevents said needle assembly from disconnecting from said catheter unit before said needle unit is displaced to said protected position.
- 41. The catheter insertion apparatus of claim 38, wherein there is a trigger start beginning defining means for prevention unconscious starting of said trigger means before said needle unit is displaced from said catheter unit to a definite given distance.
- 42. The catheter insertion apparatus of claim 38, wherein there is unidirectional needle motion means allowing said needle unit displacement only proximally with respect to said catheter unit.
- 43. The catheter insertion apparatus of claim 38, wherein there is an attachment means for fixing said catheter unit to a patient skin, and having an attachment member situated on said catheter hub.
- 44. The catheter insertion apparatus of claim 38, wherein said propelling member has distal end by which it is functionally connected with said catheter hub.
- 45. The catheter insertion apparatus of claim 38, wherein there is an actuating means for mediate control of said trigger means having at least one actuating member movable with respect to said trigger means at least between the idle position, when said actuating member is situated apart from said trigger means and proximally of it, and the trigger

position, when said actuating member is situated in the immediate vicinity of said trigger means so that actuating motion applied to said actuating member results in said trigger means start.

- 46. The catheter insertion apparatus of claim45, wherein said actuating means is made as an automatically starting actuating means, so that said actuating motion results from the continuation of said displacement of said actuating member from said idle position to said trigger position.
- 47. The catheter insertion apparatus of claim40, 46, wherein said obligatory securing means comprises said actuating means made as obligatory automatically starting actuating means, having said securing member and said actuating member functionally connected together and to said catheter unit at least until said trigger means start as a consequence of displacement of said catheter unit from said handle in distal direction or said handle from said catheter unit in proximal direction.
- 48. The catheter insertion apparatus of claim 40, 41, 42, 43, 44, 47 wherein there are:
- said handle and said guard means made integral and having a longitudinal cavity communicated to said open bore;
 - said flash chamber and said needle hub are made as an integral part,
- said trigger member made as a latch;
- said needle hub placed in said longitudinal cavity in its distal part when said needle unit is in said distal position, and said needle placed in rearward position, which is simultaneously said protected position when said needle hub is placed in proximal part of said cavity and said needle unit is retained in said rearward position by said spring;
- said securing member and said actuating member made integral as a single part slidably mounted in the guides on said handle;
- said propelling member operating as said securing member and said coupling members presenting a plurality of projections located on upper surface of said propelling member;
- said distal end of said propelling member pivotably connected to said catheter hub and after total disconnection of said catheter unit from said needle unit said

propelling member pivots by appr. I 80° around the point of its mounting to said catheter hub and is used as said attachment means for fixing said catheter unit on a patient skin;

said actuating member made as a cam adapted to moving said latch from locking position to release position;

said actuating member situated at a predetermined distance from said catheter hub and operating as a trigger start beginning defining means, since trigger means start begins when said catheter unit is removed from said needle unit by said predetermined distance;

said unidirectional needle motion means has interacting engagement members situated on said propelling member and said handle along said needle assembly longitudinal axis and made for instance as a distal edge of said propelling member and as a plurality of toothed members on said handle, to prevent return displacement of said needle unit in distal direction with respect to said catheter unit after the beginning of said needle unit moving from said extended position.

49. A catheter insertion apparatus comprising:

- a catheter unit having a catheter with a distal end, a proximal end, an open passageway therethrough, and a catheter hub affixed to the said catheter proximal end;
- a needle assembly having:
- a proximal end and a distal end adjacent to which said catheter hub being releasably connected;
 - a handle member with an open bore therethrough;
- a needle guard means, having sharp point guard with security zone;
 - a needle unit, having a tubular needle with sharp distal point, a proximal end and a needle hub affixed to said proximal needle end, said needle having an extended position, wherein said needle hub is disposed at least partly within said handle member and said needle is passing through said open bore into said catheter passageway so that said distal point of said needle projects axially beyond said distal end of said catheter, so that being in said extended position said needle is in distal position with respect to said sharp point guard wherein said sharp distal point is in maximal remote position from said sharp point guard;

- a spring interacting with said needle hub to urge said needle unit to a protected position wherein said needle sharp distal point is permanently retained within said security zone so that any accidental contact with said sharp distal point is precluded;
- a trigger means having trigger member associated with said handle member and having locking position in which it retains said needle unit in distal position relative to said handle member and releasing said needle unit when being moved in release position;
 - said handle member and said guard means made integral;
- said spring made as a coil spring coaxial around said needle, said spring is compressed between said needle hub and said handle member;
 - handle member so that after said needle unit displacement to said protected position, said shield part shifts to shielding position and thus prevents said sharp distal point displacement beyond the bounds of said security zone in distal direction;
- a restraining means preventing said sharp distal point from displacement beyond the bounds of said security zone in proximal direction when said needle unit is located in said protected position wherein said needle hub is disposed proximally of said handle member beyond it;
 - a flash chamber located in said needle hub.
- 50. The catheter insertion apparatus of claim 49, wherein said restraining means are made as an expandable sleeve interconnecting said handle member and said needle hub and placed on the outside of said spring.
- 51. The catheter insertion apparatus of claim 49, wherein there is trigger start beginning defining means for prevention unconscious starting of said trigger means before said needle unit is displaced from said catheter unit to a definite given distance.
- 52. The catheter insertion apparatus of claim 49, wherein there is a propelling means making functional interaction of said catheter unit with said needle unit and adapted to the displacement of said catheter unit in the inserting direction distally with respect to said needle unit, and/or for fixing said catheter unit in a blood vessel upon withdrawing said needle unit out of said catheter unit and disconnection of said needle assembly

from said catheter unit; said propelling means has a propelling member slidably located on exterior upper surface of said handle member, movable with respect to said needle unit, adapted to the transmission of pushing efforts to said catheter unit from the finger of the same user's hand which holds the apparatus, therewith said pushing efforts are applied to the portion of said propelling member disposed in zone of said handle member and supported immediately from below by said handle member:

- 53. The catheter insertion apparatus of claim 49, wherein: there is a trigger securing means for preventing unconscious starting said trigger means and having securing member with start trigger prevention position, wherein said trigger means start is impossible, and start trigger ready position, wherein said trigger means are ready being manually activated.
- 54. The catheter insertion apparatus of claim 53, wherein there is obligatory securing means that prevents disconnection of said needle assembly from said catheter unit before said needle unit is displaced to said protected position.
- 55. The catheter insertion apparatus of claim 53, wherein said securing member has distal end by which it is functionally connected with said catheter hub.
- 56. The catheter insertion apparatus of claim 53, wherein there is an actuating means for mediate control of said trigger means and having at least one actuating member movable with respect to said trigger means at least between the idle position, when said actuating member is situated apart from said trigger means and proximally of it, and trigger position, when said actuating member is situated in the immediate vicinity of said trigger means so that actuating motion applied to said actuating member results in said trigger means start.
- 57. The catheter insertion apparatus of claim 56, wherein said actuating means is made as an automatically starting actuating means, so that said actuating motion results from the continuation of said displacement of said actuating member from said idle position to said trigger position.

- 58. The catheter insertion apparatus of claim 54, 55, 56, wherein said obligatory securing means comprises said actuating means made as an obligatory automatically starting actuating means, having said securing member and said actuating member functionally connected together and to said catheter unit at least until said trigger means start as a consequence of displacement of said catheter unit from said handle member in distal direction or said handle member from said catheter unit in proximal direction; said securing member and said actuating member are made as an integral part slidably mounted in the guides on said handle member; said actuating member is made as a cam adapted to moving said latch from locking position to release position; said distal end of said securing member is mounted to said catheter hub; said securing member operates as said propelling means, for that it has a plurality of projections located on upper surface.
- 59. The catheter insertion apparatus of claim 49, wherein said trigger means are made as direct operated trigger member adapted for direct operation by users' fingers outside the handle member.
- 60. A catheter insertion apparatus comprising:
 - a catheter unit having a catheter with a distal end, a proximal end, an open passageway therethrough, and a catheter hub affixed to the said catheter proximal end;
 - a needle assembly having:
 - a proximal end and a distal end adjacent to which said catheter hub being releasably connected;
 - a handle with an open bore therethrough;
 - a needle guard means, having sharp point guard with security zone;
- a needle unit, having a tubular needle with sharp distal point, a proximal end and a needle hub affixed to said proximal needle end, said needle having an extended position, wherein said needle is disposed within said handle and passing through said open bore into said catheter passageway so that said sharp distal point of said needle projects axially beyond said distal end of said catheter, said needle is in distal position

with respect to said sharp point guard, and said sharp distal point is in maximal remote position from said sharp point guard;

a spring interacting with said needle hub to urge said needle unit to a protected position wherein said needle sharp distal point is permanently retained within said security zone so that any accidental contact with said sharp distal point is precluded;

a trigger means, having a trigger member associated with said handle and there are a start trigger prevention position corresponding to a locking position of said trigger member wherein it retains said needle unit in a distal position relatively said handle and a start trigger ready position wherein said trigger member can be displaced into a release position wherein it releases said needle unit;

- said guard means made as elongated guard member having a longitudinal cavity communicated to said open bore and said sharp point guard and slidably located within said handle and by its distal end, which is at the same time said needle assembly distal end, removably attached to said catheter hub;
- said handle having gripping parts placed outside of said guard member and bilaterally of it, and a handle base placed inside of said guard member;
- said gripping parts and said handle base joined together by at least one dam passing through limiting slot in the wall of said guard member;
- said needle hub placed into said longitudinal cavity in its distal part when said needle unit is in said distal position, and in said rearward position (which also serves as said protected position) when said needle hub is placed in proximal part of said cavity and said needle unit is retained in said protected position by said spring;
- in said distal position, said needle unit attached to said handle base and together they are movable along said guard member within said limiting slot in said wall of said guard member between said start trigger prevention position and said start trigger ready position in which, upon pressing said latch releases said needle unit and said spring based on said handle base propels said needle unit in proximal direction relatively said guard member to said protected position, and on reaching it, said spring propels said guard member and said needle unit together proximally relative to said handle until said guard member reaches extreme proximal position relative to said handle and is held in this position by said spring.

- 61. The catheter insertion apparatus of claim 60, wherein there is a trigger securing means preventing unconscious starting said trigger means and having a securing member with said start trigger prevention position wherein said trigger means start is impossible and with said start trigger ready position wherein said trigger means are ready to be activated.
- 62. The catheter insertion apparatus of claim 61, wherein there is a propelling means making functional interaction of said catheter unit with said needle unit and adapted to the displacement of said catheter unit in the insertion direction with respect to said needle unit; said propelling means are operated by the same user's hand which holds the apparatus.

and the first the transfer exercise an grown as the contract suggestion of the contract of the

- 63. The catheter insertion apparatus of claim 62, wherein said needle unit has a flash chamber located adjacent to said needle hub.
- 64. The catheter insertion apparatus of claim 63, wherein said trigger member is made as a latch.
- 65. The catheter insertion apparatus of claim 64, having a stopping means for stopping said securing member in said start trigger ready position, which are made as a proximal edge of said dam and a distal edge of said limiting slot.
- 66. The catheter insertion apparatus of claim 65, wherein said trigger means has direct operated said trigger member adapted to direct operation by user's fingers outside the handle and provided with a button.

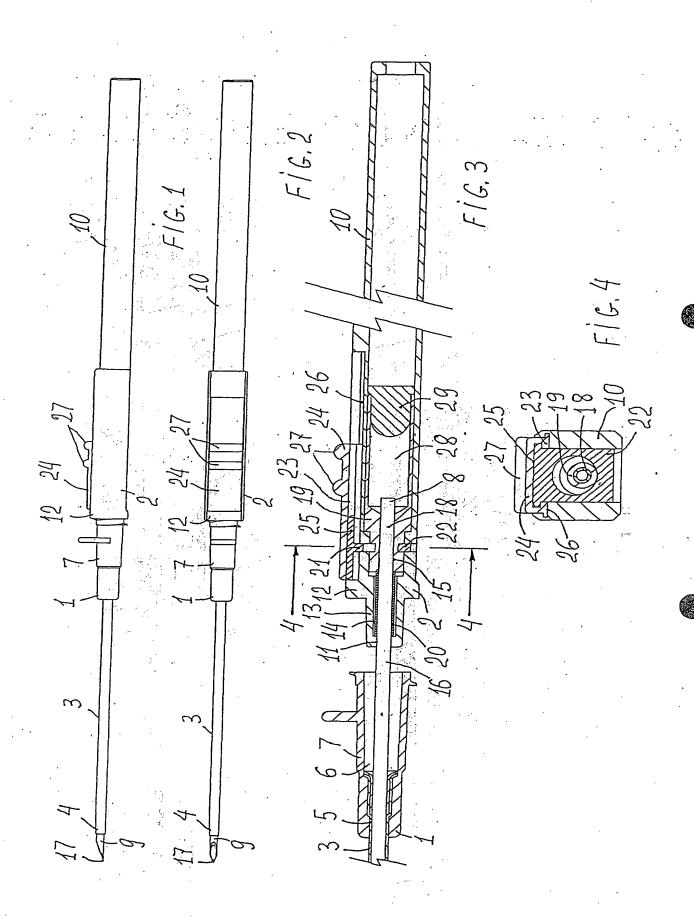
Grand Stanton Commence of Carlot Age

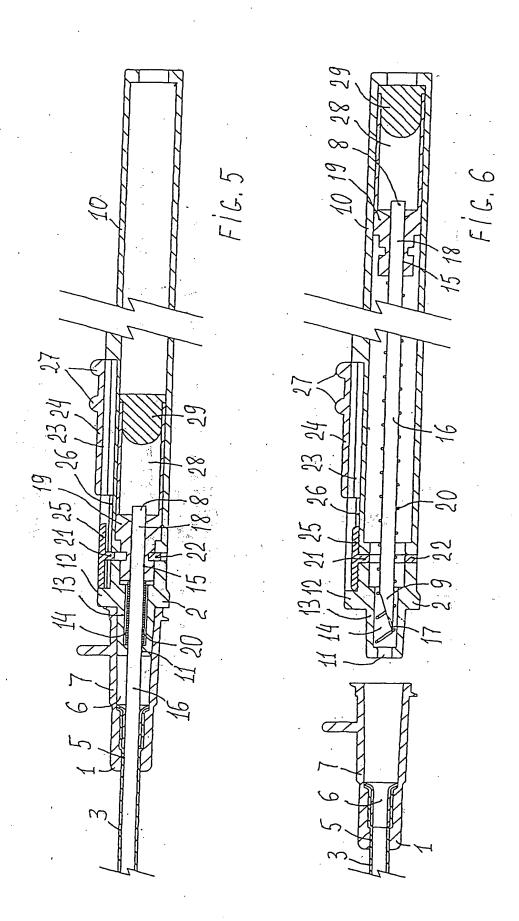
in the transfer of the second of the

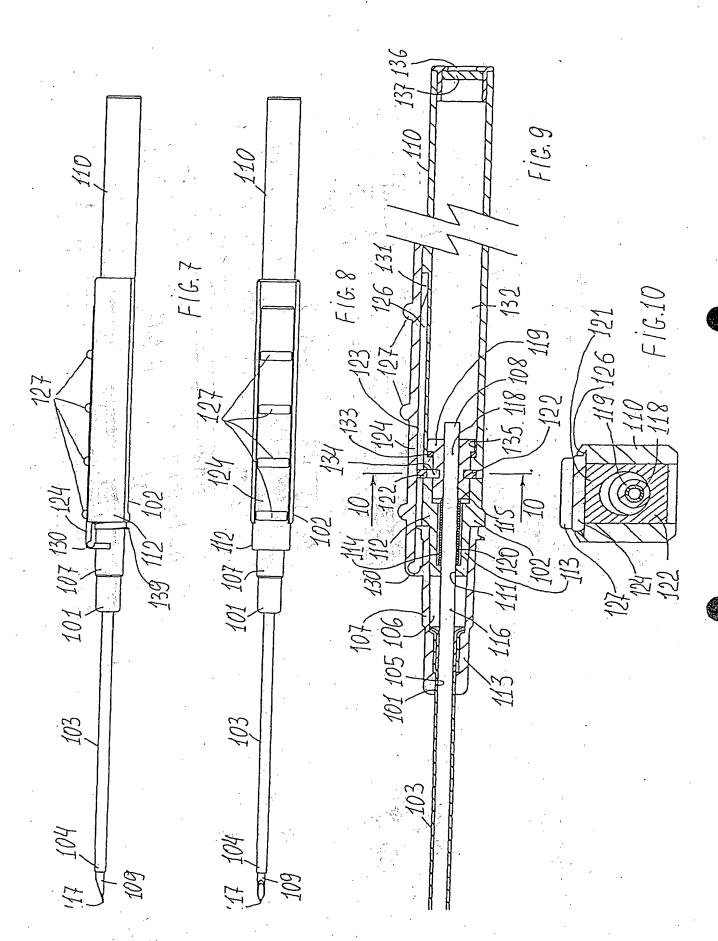
- 67. The catheter insertion apparatus of claim 64, wherein said securing member is made as a securing lock member, which in said start trigger prevention position locks said trigger member, precluding said trigger means start and unlocks said trigger member, being transferred to said start trigger ready position.
- 68. The catheter insertion apparatus of claim 64, wherein there is an actuating means for mediate control of said trigger means having at least one actuating member movable

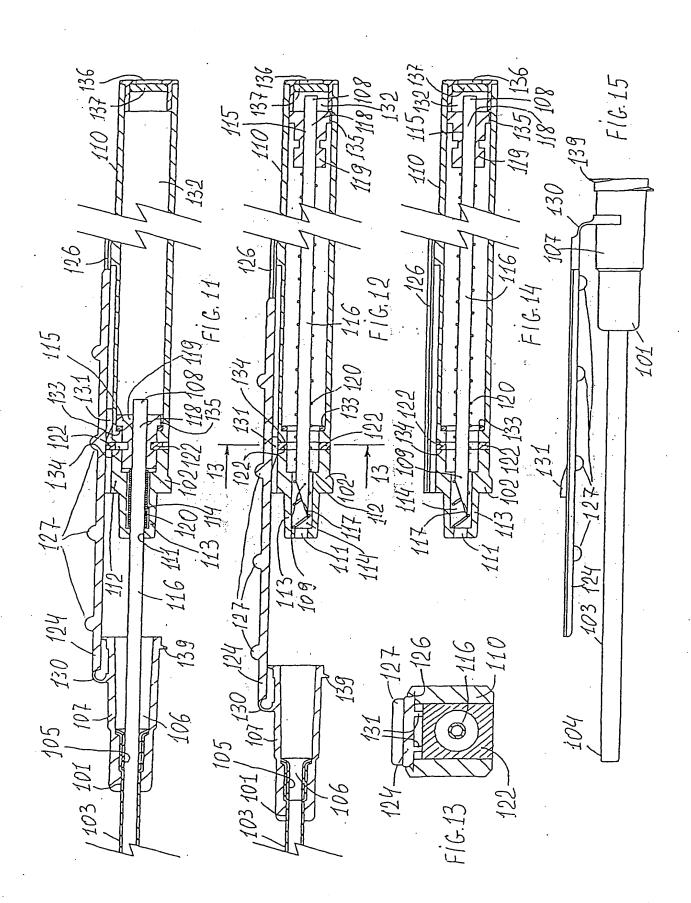
with respect to said trigger means at least between the idle position, when said actuating member is situated apart from said trigger means and proximally of it, and the trigger position, when said actuating member is situated in the immediate vicinity of said trigger means so that actuating motion applied to said actuating member results in said trigger means start.

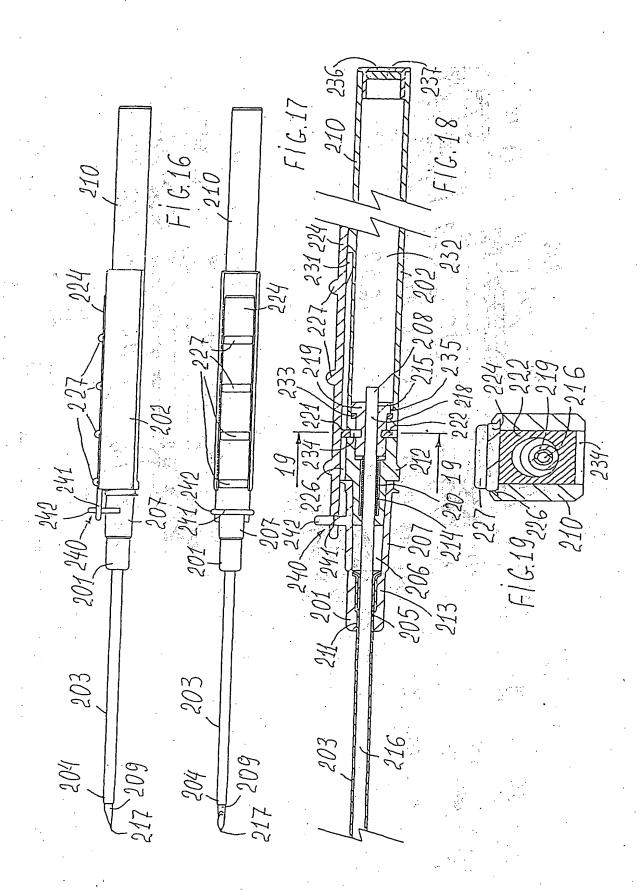
- 69. The catheter insertion apparatus of claim 65, 68, wherein said actuating member made as a pusher placed on said guard member and adapted, upon being pressed on, to displace of said latch from said locking position to said release position.
- 70. The catheter insertion apparatus of claim 68, wherein said actuating means is made as an automatically starting actuating means, so that said actuating motion results from the continuation of said displacement of said actuating member from said idle position to said trigger position.
- 71. The catheter insertion apparatus of claims 3, 4, 5, 6, 17, 18, wherein:
- said actuating member is made as a cam adapted to moving said latch from locking position to release position;
 - said actuating member is situated at a predetermined distance from said catheter hub and operate as trigger start beginning defining means, since trigger means start begins with said catheter unit estranging from said needle unit by the same distance;
- said unidirectional needle motion means, having interacting engagement members situated on said guard member and on the detail movable with respect to said guard member along the longitudinal axis of said needle assembly and made for instance as a plurality of toothed members on said guard member and as a distal edge of said handle to prevent return displacement of said needle unit in distal direction with respect to said catheter unit after the beginning of said needle unit moving from said extended position.

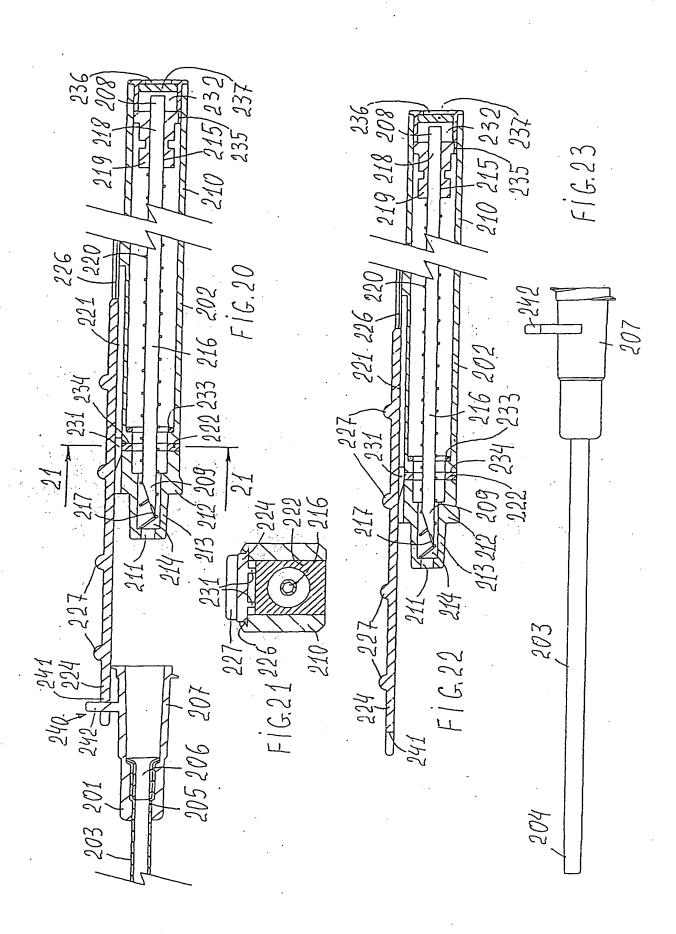




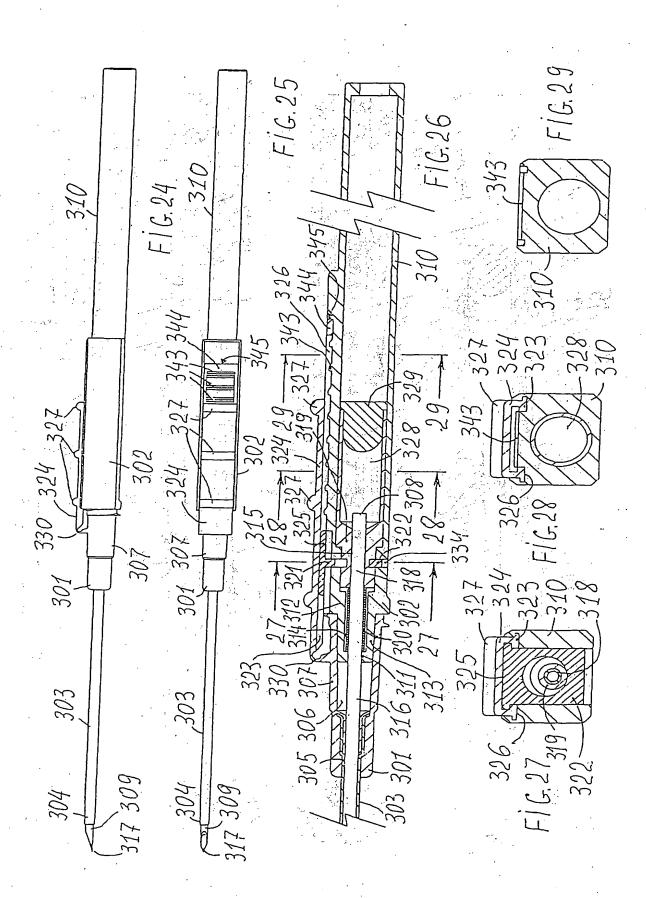


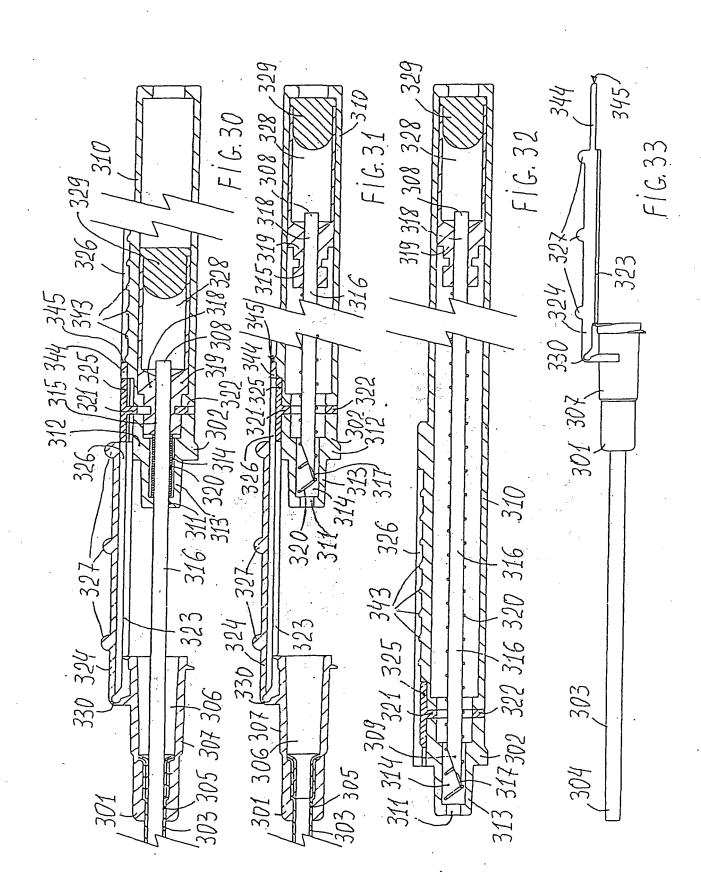


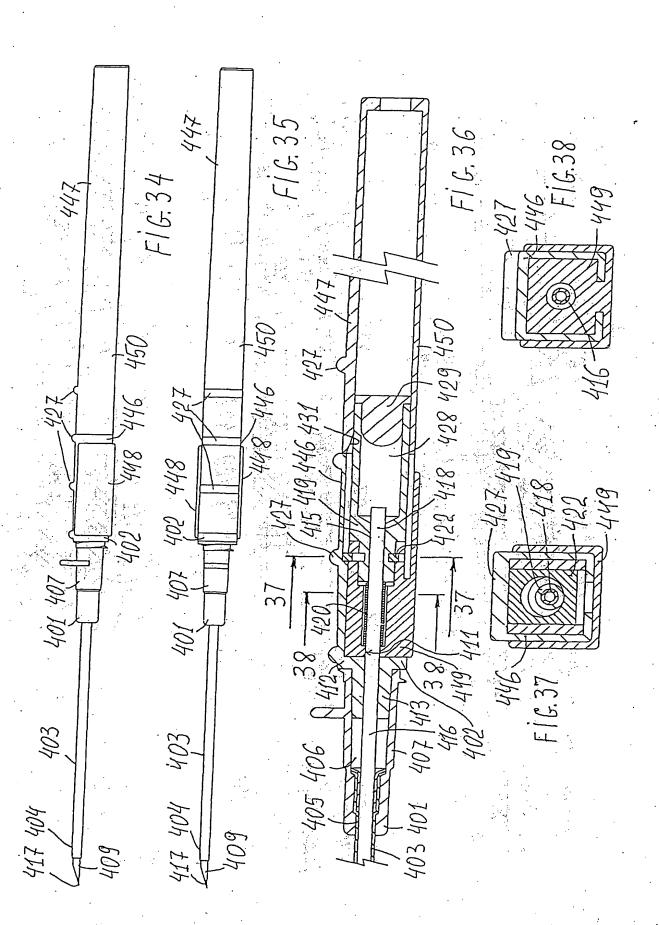


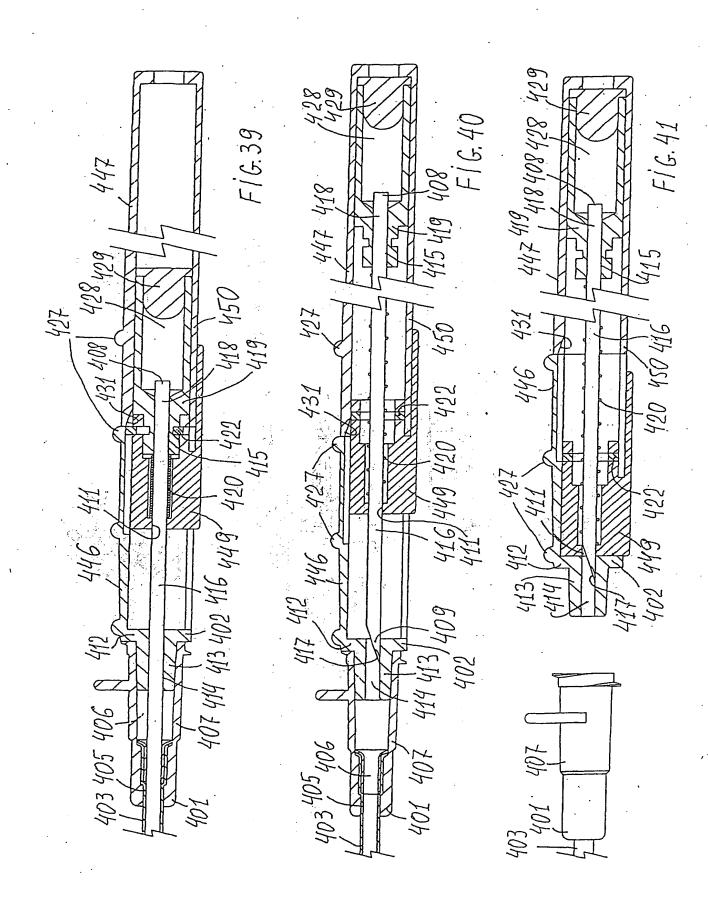


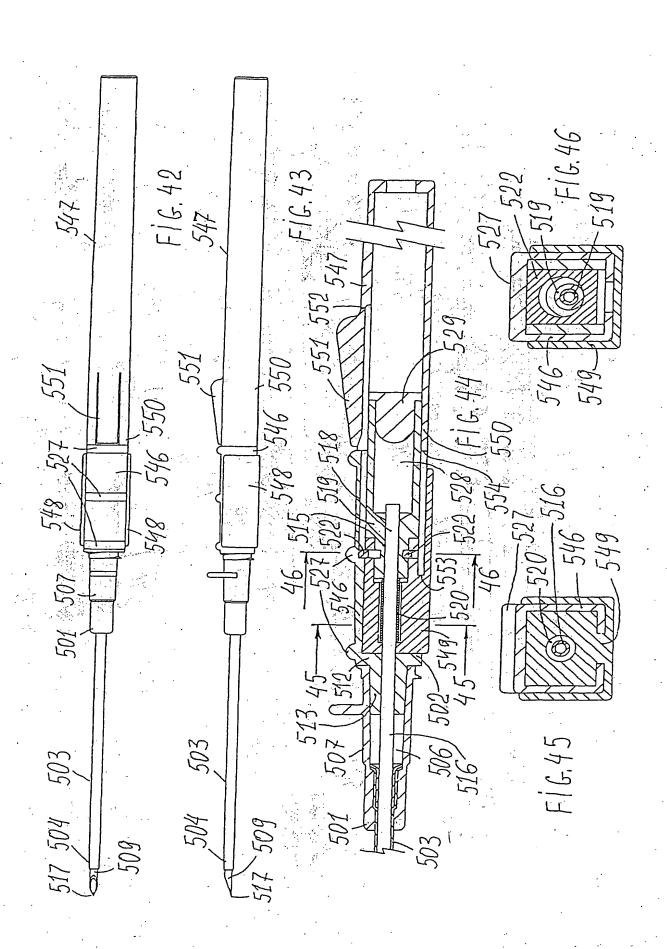
900010- -WO 0241932A2 I

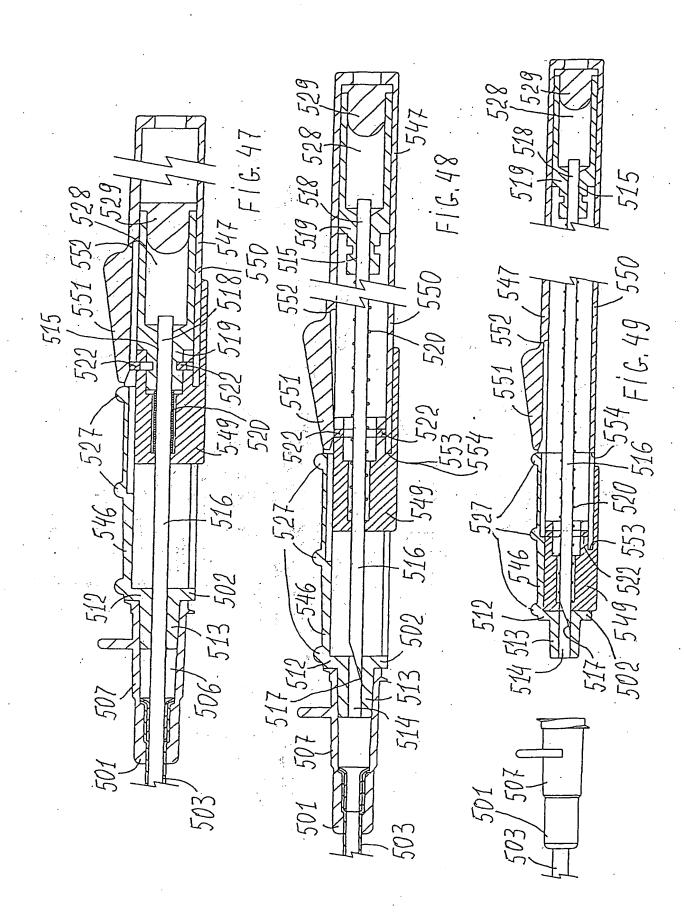


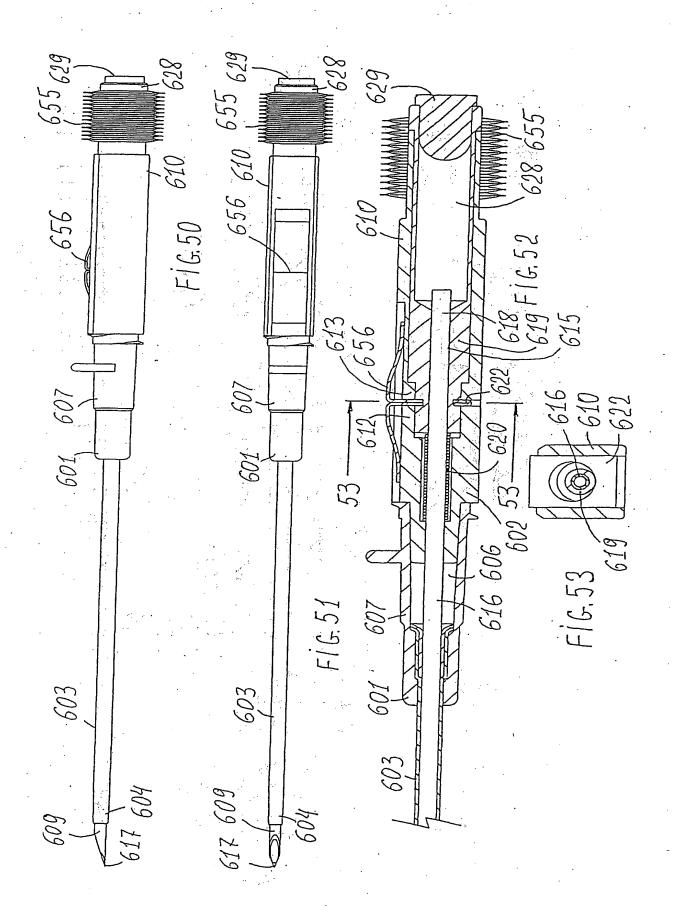


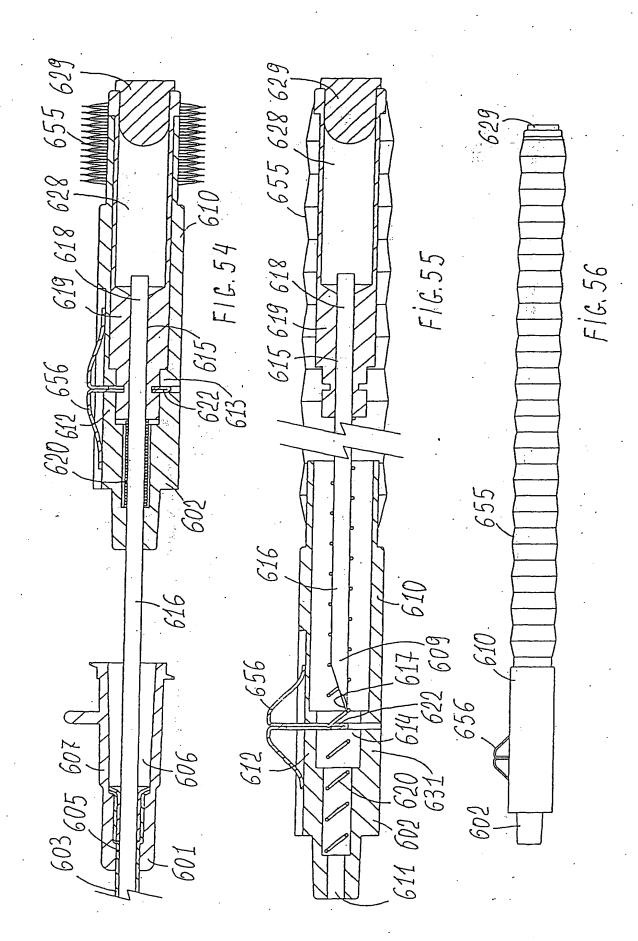


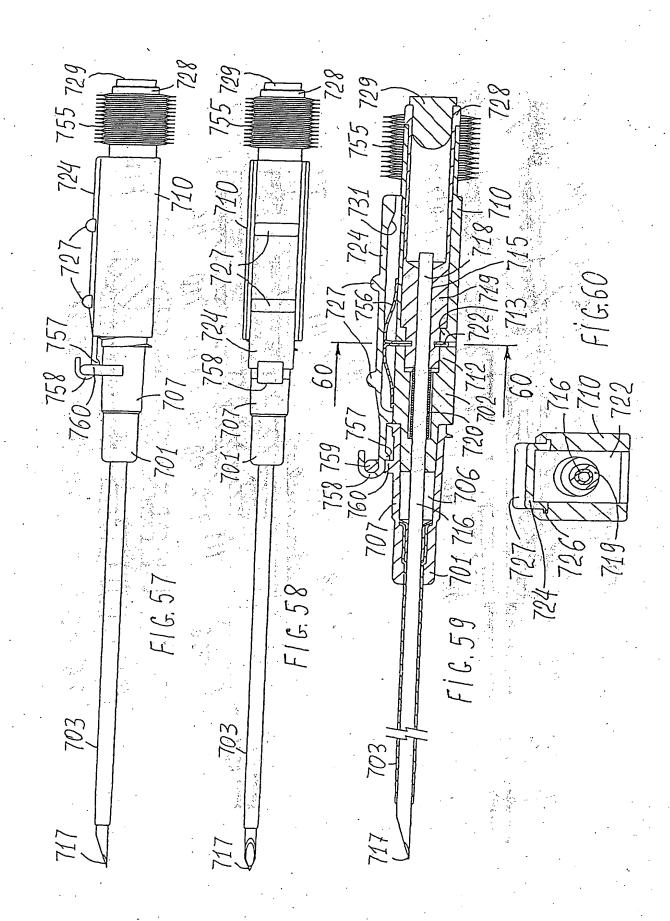


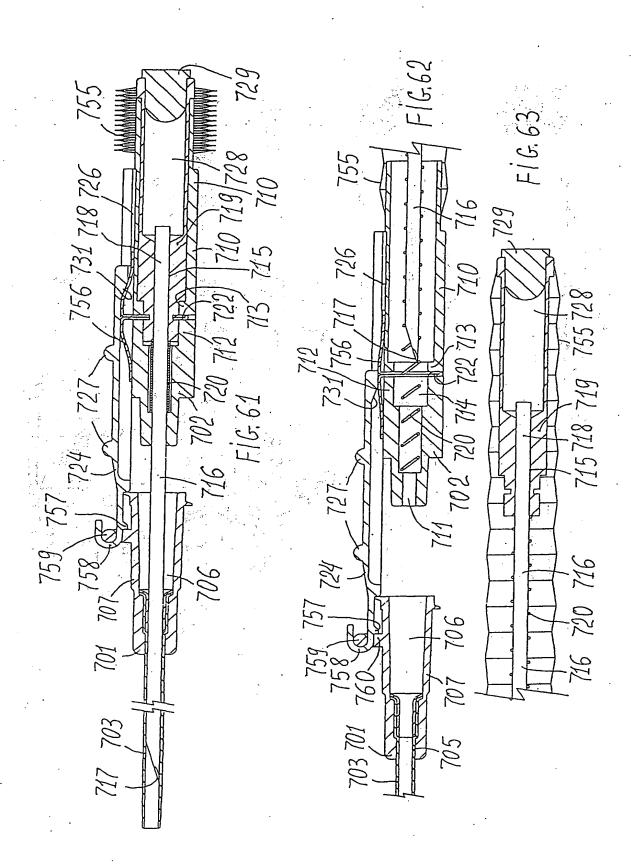


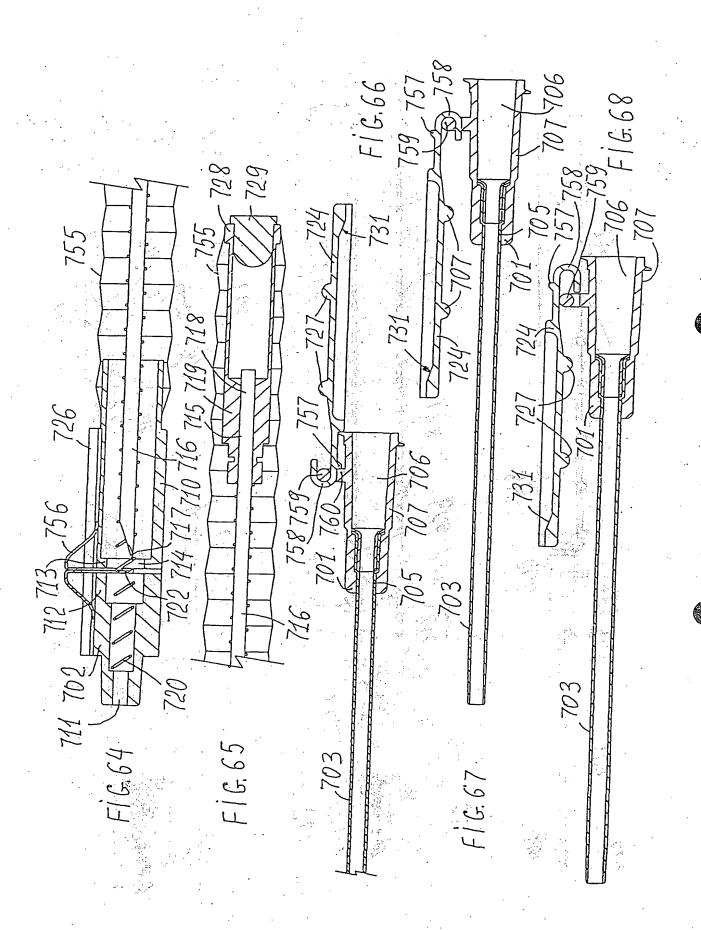


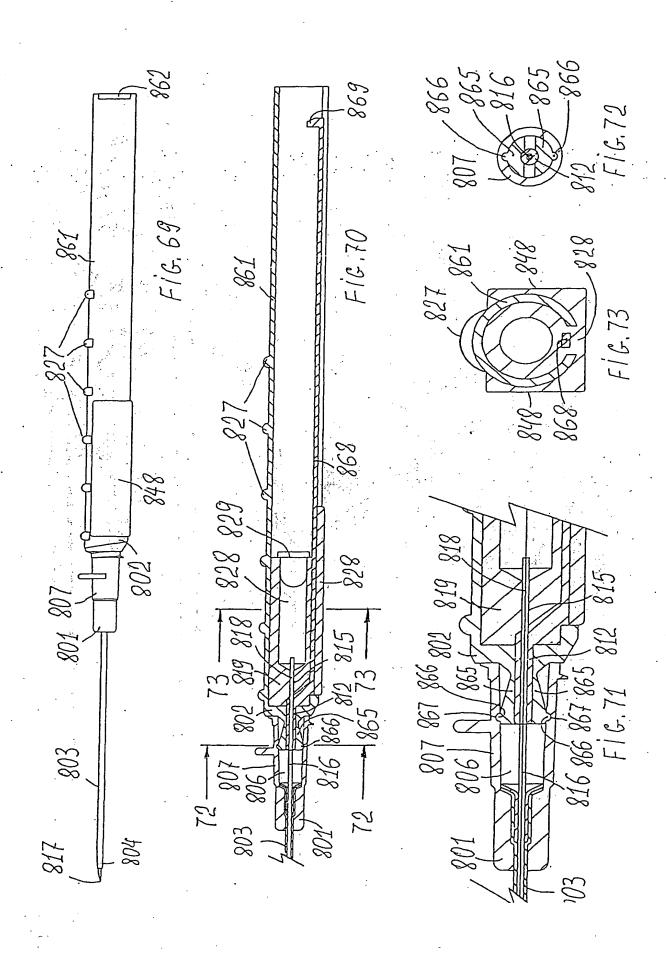


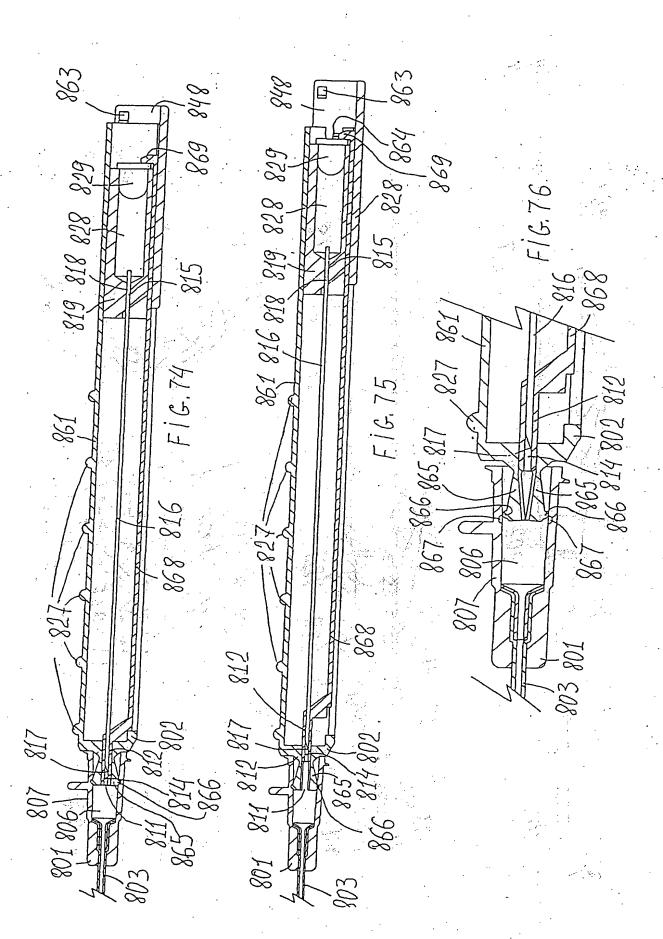


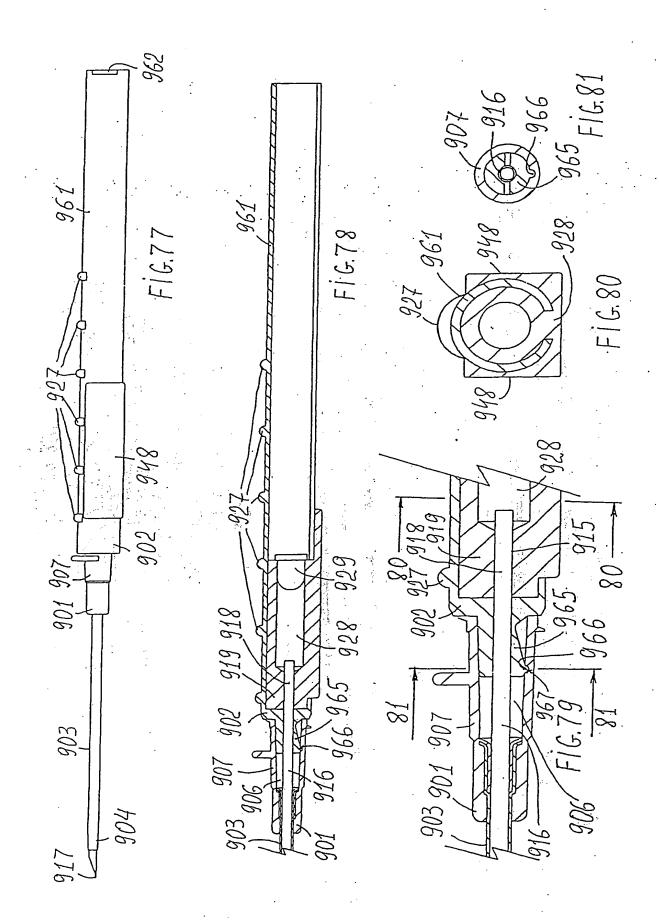


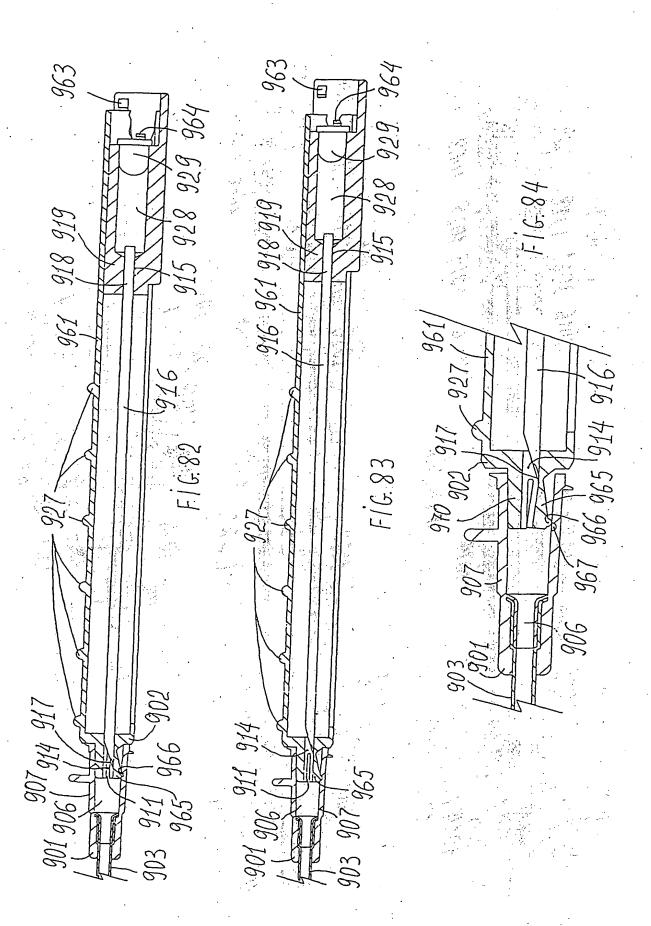


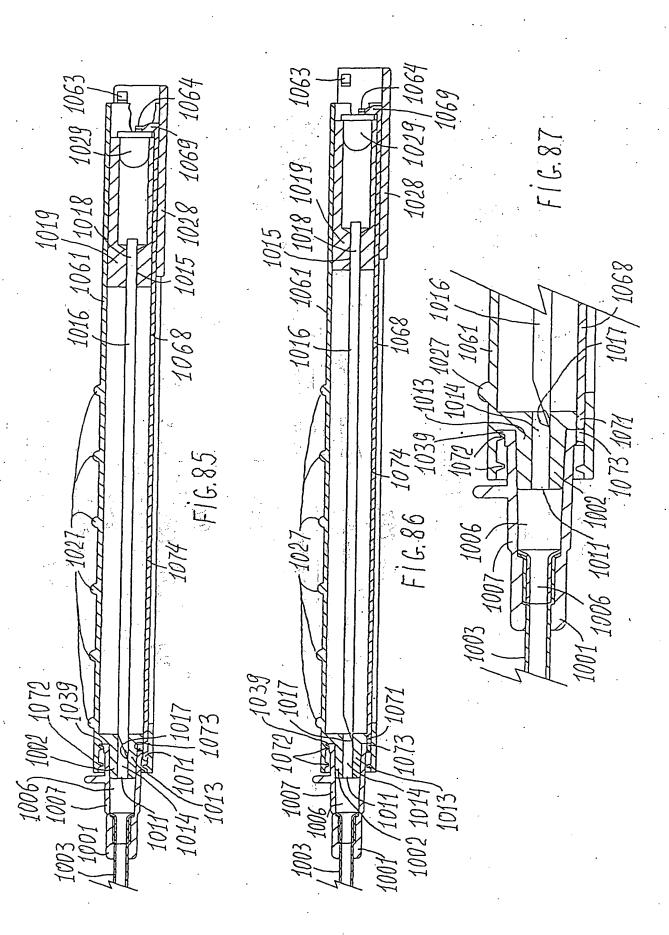


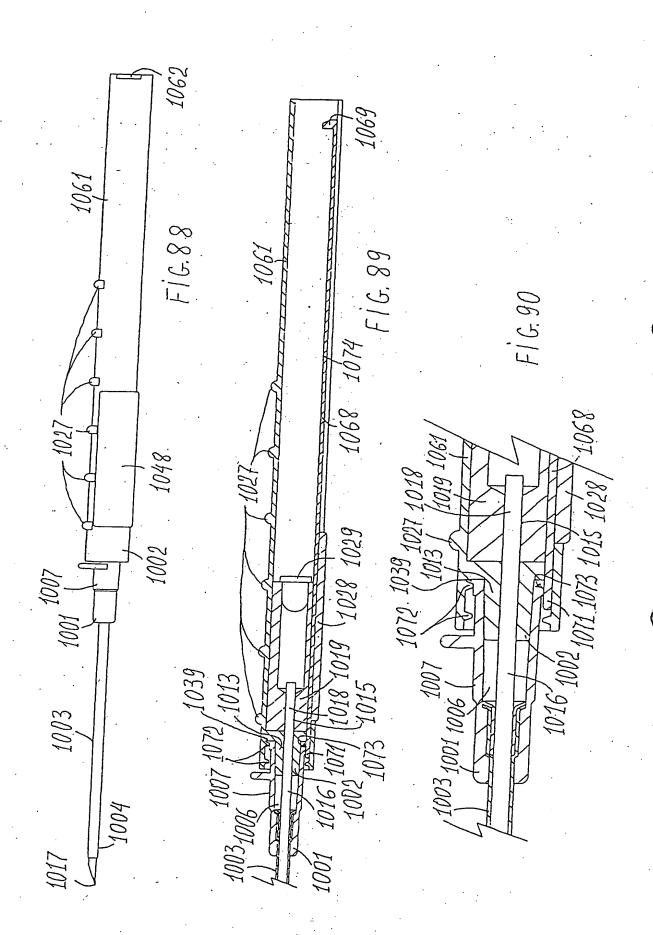












THIS PAGE RI ANK (USPTO)

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

| ·, |
|---|
| ☐ BLACK BORDERS |
| ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES |
| FADED TEXT OR DRAWING |
| ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING |
| ☐ SKEWED/SLANTED IMAGES |
| ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS |
| ☐ GRAY SCALE DOCUMENTS |
| ☐ LINES OR MARKS ON ORIGINAL DOCUMENT |
| ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY |
| ☐ OTHER: |

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

